EXHIBIT 8

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

DePuy Mitek, Inc. **a Massachusetts Corporation** **Plaintiff,** **v.** **Arthrex, Inc.** **a Delaware Corporation and** **Pearsalls Ltd.,** **a Private Limited Company** **of the United Kingdom,** **Defendants.**	)	**Civil No. 04-12457 PBS**

Expert Report of Dr. Matthew Hermes

I. Background Information

A. Professional Experience

1. From 1983-95, I was employed with U. S. Surgical Corp. In 1983, I started as Senior Research Scientist. My duties from 1983-1986 included developing products based on bio-absorbable materials for use as medical devices. From 1986-1992, I initiated and led the first suture development program at U.S. Surgical. That program led to the commercialization of the Syneture™ suture product line. My responsibilities included all phases of surgical suture development from concept to commercialization. My suture group included seventeen team members directly involved in the design and development of commercial surgical suture products, including suture design and manufacture, fiber extrusion and processing, fiber design, yarn design, braiding specifications, selection of materials, braid design, prototype braiding, braid post

treatment, stretching, annealing, coating, packaging design, sterilization, testing, assisting with obtaining 510(k) approval, and quality control.

2. In 1996, I authored the book “Enough for One Lifetime,” the biography of Wallace Carothers, the inventor of Nylon. While writing this book from 1989-1996, I researched and studied the origins of synthetic fiber science including the history and development of nylon and polyester.

3. Before I worked at U.S. Surgical Corporation, I was a Research Director at Virginia Chemicals, at Celanese Co. from 1979-1983. Prior to being a Research Director, I was a Research Chemist, Supervisor, at E. I. DuPont from 1959-1979. At DuPont, I work with triaxial support systems and supervised a group that worked on elastomer coated fabrics.

4. From 1992-1994, I was an Adjunct Professor of Chemistry at the University of Wyoming. From 1995-1997, I was a Consultant at Colorado Advanced Technology Institute. In 2001 and 2006, I received two Small Business grants from the NIH for the development of unique all plastic manual wheelchairs and worked with Turbo Wheelchair company to develop, manufacture, and sell these unique devices.

B. Education

5. I have a Bachelor of Science in Chemistry from St. John's University, Brooklyn, NY, 1955. I have a Ph. D. in Chemistry from the University of Maryland, 1959. My mentor was Professor William Bailey who developed one of the earliest polymer science research groups in the country. My doctoral thesis related to polymers made using the Diels-Alder reaction. I also have a Masters of Arts in Liberal Studies from Wesleyan University,1992.

6. A copy of my CV is attached under Ex. 1. A list of my publications and patents are set forth in my CV. In the past four years, I have not been deposed or testified as an expert witness.

7. I am being compensated at my customary hourly rate of $200/hr. My compensation is not based on the outcome of the litigation.

II. Summary of Opinions

8. It is my opinion that claims 1, 2, 8, 9, and 12 of U.S. Patent No. 5,314,446 Patent ("the 446 Patent) (Ex. 2) are not invalid for obviousness over U.S. Patent No. 4,610,688 ("the 688 patent") when combined with U.S. Patent No. 5,120,802 ("the 802 patent"), the Dyneema SK60, High strength/high modulus fiber, Properties & Applications ("the DSM brochure")[1]; and/or the general teachings of the art as defined by Dr. Mukherjee.[2]

9. It is my opinion that claims 1, 2, 8, 9, and 12 of the 446 Patent are not anticipated by U.S. Patent No. 5,318,575[3] ("the 575 patent") because the 575 patent does not teach, either expressly or inherently, all of the claimed limitations of these claims.

10. If the claims of the 446 Patent are construed to mean that "PE" includes UHMW PE, it is my opinion that claims 1, 2, 8, 9, and 12 of the 446 Patent are not invalid for obviousness over U.K. patent application No. 2,218,312A to Burgess ("Burgess") and i) Cohan, et al., An Evolution of Ultrastrong Polyethylene Fiber as an Ophthalmic Suture, Arch Ophtalmol – Vol. 103, December 1985 ("Cohan"); ii) the DSM brochure; and/or iii)

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[1] I understand that there are legal requirements for whether a document qualifies as prior art. I also understand that the DSM Brochure may not be prior art. For purposes of this report, I have been asked to assume that it qualifies as prior art.

[2] Dr. Mukherjee does not opine on the validity of claims 3-7 and 10-11 of the 446 over the references that he cites. I was not asked to consider the validity of claims 3-7 and 10-11 of the 446 patent over the references cited by Dr. Mukherjee.

[3] I understand that there are legal requirements for whether a document qualifies as prior art. I also understand that Chesterfield may not be prior art. For purposes of this report, I have been asked to assume that Chesterfield qualifies as prior art.

either one of U.S. Patent No. 4,563,392 or U.S. Patent No. 4,543,286 ("Harpell patents").

11. If the claims of the 446 Patent are construed to mean that "PE" includes UHMW PE, it is my opinion that the claims of the 446 patent are not invalid for failing to satisfy the written description requirement because the 446 Patent specification describes the claimed invention sufficiently to convey to a person of skill in the art, that the inventors had possession of the sutures recited in the 446 patent claims, at the time the patent application for the 446 patent (February 1992) was filed with the U.S. Patent & Trademark Office.

12. If the claims of the 446 Patent are construed to mean that "PE" includes UHMW PE, it is my opinion that the claims of the 446 Patent are not invalid for failing to satisfy the enablement requirement because the claimed invention is sufficiently disclosed, such that a person of skill in the art, at the time the patent application for the 446 patent was filed with the U.S. Patent & Trademark Office (February 1992), could make and use the sutures claimed in the 446 Patent, without undue experimentation based on the 446 patent's description of the claimed sutures.

13. It is my opinion that the inventors actually reduced to practice the inventions recited in claims 1, 8, and 9 of the 446 Patent at least as early as February 1989 and certainly at least as early as December 1989.

14. It is my opinion that, Mr. Goodwin's and Dr. Steckel's statements, that Mr. Witherspoon said were materially inconsistent were not inconsistent, much less materially inconsistent.

15. I may testify about certain suture properties and suture testing.

III. Legal Framework for My Opinions

16. The patent laws form the legal framework for my opinions. My understanding of the U.S. Patent Laws is as follows. I understand that the patent statute states that patents are presumed valid. 35 U.S.C. §282. I further understand that each patent claim is presumed valid, and therefore an invalidity analysis must be done on a claim-by-claim basis. I understand that because of this presumption, Arthrex or Pearsalls must put forth "clear and convincing" evidence of invalidity to overcome this presumption of validity. It is my understanding that this a higher burden of proof than a preponderance of the evidence standard, but less than a reasonable doubt standard.

A. The Law of Anticipation

17. It is my understanding that a patent claim is invalid if it is not novel (which I understand is referred to as being "anticipated"), if a single prior art reference teaches, expressly or inherently (necessarily present), all of the claim limitations arranged in the same manner as the claim and enables one of ordinary skill in the art to make and use the invention. I understand that the test for lack of novelty is generally a two-part test. First, the meaning and scope of the claims are determined by the Court. Second, once the claim scope has been determined or construed, the next step in assessing a patent claim's validity is deciding whether one piece of prior art describes all of the claim limitations arranged as claimed. Because the Court has not yet construed the claims of U.S. Patent No. 5,134,446, I have been asked to assume a certain claim construction.

B. The Law of Obviousness

18. I also understand that a claim is invalid due to obviousness under 35 U.S.C. §103 if there is clear and convincing evidence showing that the differences between the claim and the prior art are such that the claimed subject matter as a whole would have

been obvious to a person having ordinary skill in the art at the time the invention was made.

19. I understand that determining obviousness involves the following four factual inquires: 1) the scope and content of the relevant prior art; 2) the level of ordinary skill in the art; 3) the differences between the claimed invention and the prior art; and 4) secondary considerations of non-obviousness.

20. I understand that the "scope and content of the relevant prior art" includes all art that is reasonably pertinent to the particular problem with which the invention was involved. In other words, the relevant art is defined by the nature of the problem confronting the would-be inventor. The relevant prior art encompasses art in the inventor's field of endeavor and any analogous art.

21. I understand that "analogous prior art" is art that, although not within the inventor's field of endeavor, is still reasonably pertinent to the particular problem to be solved. I understand that a reference is "reasonably pertinent" if, even though it may be in a different field from that of the inventor's endeavor, it is one which, because of the matter with which it deals, logically would have commended itself to an inventor's attention in considering the problem.

22. In the case where obviousness is based on the combination of prior art references, I understand that there must be a reason, suggestion, or motivation in the prior art or elsewhere, that would have led a person of ordinary skill in the art to combine the prior art references to arrive at the claimed invention. The relevant inquiry is whether a skilled artisan, confronted with the same problems as the inventor, and with no knowledge of the claimed invention, would select the elements from the prior art for

combination in the manner claimed. In selecting prior art references relevant to the obviousness inquiry, it is considered improper "hindsight" to define the problem to be solved in terms of its solution (*i.e.*, the claimed invention).

23. I also understand that it is not enough to find every element of a claimed invention in the prior art. There must be a reason, suggestion, or motivation to combine the prior art in such a way so as to arrive at the claimed invention.

24. I understand that so-called "secondary considerations of non-obviousness," when present, must also be considered as part of the obviousness determination. I understand that these are objective evidence of non-obviousness, and include, among other things, evidence of commercial success, copying, long-felt but unresolved need, failure of others, unexpected results created by the claimed invention, unexpected properties of the claimed invention, licenses showing industry respect for the invention, skepticism of persons skilled in the art before the invention, and tribute by others. These secondary considerations provide objective evidence of how the patented device is viewed in the marketplace by those directly interested in the product.

C. The Law of Written Description & Enablement

25. I understand that another condition of validity is that a patent must describe the invention sufficiently to convey to a person of skill in the art that the patentee had possession of the claimed invention at the time of the application, *i.e.*, that the patentee invented what is claimed.

26. I understand that another condition of validity is that a patent must describe the manner and process of making and using the invention so as to enable a person of skill in the art to make and use the invention without undue experimentation. I understand that routine details do not need to be disclosed in a patent because they are readily

apparent to one of ordinary skill in the art and that patent specifications need not be as detailed as production specifications.

D. Actual Reduction to Practice

27. I understand that invention requires a conception and reduction to practice. I understand that conception is the formulation of an idea in one's mind of a definite and permanent idea. I further understand that actual reduction to practice typically occurs when the claimed invention is constructed and evaluated sufficiently to know that it will work for its intended purpose.

IV. Claim Construction

28. As mentioned above, I understand that the first step in an invalidity analysis is to determine the meaning of the claims. I understand that the Court will determine the meaning of the claim terms in the 446 Patent. Until the Court determines the meaning of the claims, I have been asked to assume the meaning of the following claim terms.

"PE" – means all types of polyethylene (PE) including ultra high molecular weight polyethylene.

"Consisting essentially of" – means the claimed suture with all of its limitations and any other unlisted materials that do not materially affect the basic and novel characteristics of the claimed suture.

I have been told that the Court will determine the basic and novel characteristics of the claimed invention. I have been asked to assume that the basic and novel characteristics are a heterogeneous braid of dissimilar non-bioabsorbable yarns of the type claimed, where at least one yarn from the first set is in direct intertwining contact with a yarn from the second set, and the dissimilar yarns have at least some different properties that contribute to the overall properties of the braid.

"Direct intertwining contact" means the mechanical interlocking or weaving of the individual yarns that make up the suture braid.

"Volume fraction of the first set of yarns in the braided sheath and core" means the ratio of the cross-sectional area of the first set of yarns in the sheath and core to the total cross sectional area of all the yarns in the surgical suture.

I reserve the right to modify my opinion should the Court determine the meaning of the claims are different than the above constructions.

V. Materials Considered in Forming My Opinions

29. In forming my opinions, I have considered the 446 Patent, its file history, and the reports of Dr. Debi Prasad Mukherjee and John F. Witherspoon, and Peter Dreyfuss's, Brian Hallet's, and Dr. Mark Steckel's, and Mr. Donald Grafton's deposition testimony. A list of the documents that I used in forming my opinions is set forth in Ex. 16.

VI. Claims 1, 2, 8, 9, & 12 of the 446 Patent Are Not Invalid Over the References Discussed by Dr. Mukherjee

A. The Level Of Ordinary Skill In The Art

30. I understand that Dr. Mukherjee has opined that a person of ordinary skill in the art, "in February 1992, had an undergraduate degree in engineering or science and several years (*e.g.*, approximately 3-5) experience with manufacturing and/or processing of fibers and sutures which can be used for biomedical applications." (Mukherjee at 10). I disagree because this definition of ordinary skill is too broad. It encompasses persons who do not have any relevant technical degrees and relevant experience. For example, Dr. Mukherjee's definition includes someone with no education that is relevant to suture design and no suture design experience.

31. In my opinion, between 1988-1992, a person of *ordinary* skill in the art would likely be a scientist in chemistry or a chemical, mechanical, or biomedical, biomechanical, or textile engineer (or other similar technical field) practicing in the field of suture design or development and having about 2 to 3 years of experience in the suture design field or person without such a degree but having about eight years experience in suture design or development. In my opinion, between 1988-1992, a person of skill in the art would likely be a scientist in chemistry or a chemical, mechanical, or biomedical, biomechanical, or textile engineer (or other similar technical field) practicing in the field of suture design or development and having about 1 to 2 years of experience in the suture design field or person without such a degree but having about five years experience in suture design or development.

32. Both the person of ordinary skill in the art and the person of skill in the art would have known that a broad spectrum of sutures were available for surgical use between 1988-1992. During that period of time, commercial sutures generally were classified as either monofilaments or multifilaments.

33. Both the person of ordinary skill in the art and the person of skill in the art would also have known that sutures are designed based on a balance of several properties including, among others, knot strength, knot security, pliability, tissue drag, run down, absorbability, and biocompatibility. Also, one of ordinary skill in the art would have understood that generally monofilaments and multifilaments possessed different properties giving them advantages and disadvantages over each other. For example, generally, monofilaments had less tissue drag, but would lack relative pliability and knot security, when compared to multifilaments. Whereas, multifilaments, generally, would

be more pliable and have greater knot security, but relative poor knot run down and tissue drag, when compared to monofilaments.

B. Claim 1 of the 446 Patent Is Not Invalid For Obviousness Over The 688 Patent When Combined With The 802 Patent, the DSM Brochure, And/Or The General Teachings Of The Art As Defined By Dr. Mukherjee

34. I understand that Dr. Mukherjee has opined that claims 1, 2, 8, and 12 of the 446 Patent are invalid as obvious over the 688 patent when combined with the 802 patent, the DSM Brochure and/or the general teachings of the art as defined by Dr. Mukherjee (Mukherjee at 3, 13). I disagree with Dr. Mukherjee's opinions for the reasons set forth below.

1. The Scope And Content Of The 688 Patent, The 802 Patent, & The DSM Brochure

35. Below I discuss the scope and content of the 688 patent, the 802 patent, and the DSM brochure as they would have been understood by a person of ordinary skill in the art between 1988 and 1992.

a) The Scope & Content of the 688 Patent

36. The 688 patent teaches a ligament prosthesis, not a suture (Ex. 3 at 2:14). Dr. Mukherjee agrees (Mukherjee at 11). According to the 688 patent, the disclosed ligament prosthesis is designed to have a "yield strength in tension and a longitudinal elasticity that are at least as comparable to that of a human ligament and a resistance of longitudinal elastic deformation in tension that approximates that of a human ligament" (Ex. 3 at 2:16-19). The 688 patent teaches a tubular triaxial-fabric braided element (Ex. 3 at 3:49-50) having three sets of fibers, designated 9,11, and 13 (Ex. 3 at 3:65-66). Fibers 9 are straight, and fibers 11 and 13 are helically disposed in the wall of the tubular fabric prosthesis (Ex. 3 at 3:66-4:3). The 688 patent teaches that the straight

fibers 9 are made from a group of materials one of which is hard elastic polypropylene (Ex. 3 at 5:50-57). Fibers 11 and 13 are made from a different group of materials, but are taught to be the same in a given prosthesis (Ex. 3 at 5:57-6:2; Table of Fibers). The triaxial braid taught by the 688 patent is manufactured on a triaxial braiding machine (Ex. 3 at 4:14-36).

b) The Scope & Content of the 802 Patent

37. The 802 patent describes that the potential biological or medical uses of block copolymers having carbonates as their major component had not been appreciated (Ex. 4 at 1:35-36). Accordingly, the 802 patent teaches a polycarbonate-based, block copolymer having at least one flexible block and at least one block, which is more crystalline than the first flexible block (Ex. 4 at 1:6-9). The 802 patent provides examples of the two blocks, which it refers to as “A” and “B” blocks (Ex. 4 at 2:47-3:60). It provides a more detailed description of specific block copolymers throughout the patent (Ex. 4 at 4:8-44; 4:48-12:30). The main focus of the 802 patent to one of ordinary skill in the art between 1988 and 1992 is specific block-copolymer structures that may have useful applications.

38. According to the 802 patent, the block copolymers that it teaches are “particularly suited to be spun into fibers, extruded into films, tubings, and devices of many shapes and sizes” (Ex. 4 at 1:9-12; see also 12:55-65). The 802 patent describes many general applications for the block polymer including forming fibers or yarns that may be “woven, braided and/or knitted into fabrics having various structural configurations” (Ex. 4 at 15:41-42). Also, the 802 patent states that the block copolymers can be formed into fibers that are “preferably used as sutures or fasteners” (Ex. 4 at 15:44-45). The 802 patents states that the block copolymers that are “particularly useful are woven or

knitted fabrics in the form of tubular prostheses of varying shapes, lengths, and diameters" and illustrative of these tubular prosthesis are "vascular grafts, nerve guidance channels, and the like" (Ex. 4 at 15:60-62).

c) The Scope & Content of the DSM Brochure

39. DSM is a company that manufactures fibers for use in different applications. The DSM brochure advertises that Dyneema SK60 can be used for many different applications, including, cable, bow strings, ropes, strings, sutures, ligaments and long line and sport sea fishing (Ex. 5 at PR08424). The DSM brochure describes that polyethylene properties cover the range from 1 N/tex specific strength and 25 N/tex specific modulus to 3.5 N/tex specific strength and 150 N/tex specific modulus (Ex. 5 at PR08422). It also notes that Dyneema SK60 falls within this range at 2.7 N/tex and 90 N/tex (Ex. 5 at PR08422). Accordingly to the brochure, the Dyneema SK60 was a new material, and it further notes the knot strength of certain SK60 fibers, not braids (Ex. 5 at PR08426). The brochure does not mention knot security, provide any analysis regarding the knot security of Dyneema SK60N, or provide any specific analysis of properties associated with braids (Ex. 5).

40. There is no discussion in the Dyneema brochure of a heterogeneous braid. There is no discussion in the DSM Brochure of using PET, Nylon, or aramid in combination with UHMW PE fibers. Further, there is no description of how to construct braids or using Dyneema fibers to make braided sutures.

41. I note that the DSM brochure provided with Dr. Mukherjee's report (Ex. 7 of Mukherjee report) is not completely readable. For example, the knot strengths of the fibers are not readable. Thus, I am not able to comment on the teachings of the DSM

brochure as a whole. I understand, however, that a reference is supposed to be considered as a whole based on all of its teachings.

2. The Differences Between The 688 Patent, the 802 Patent, the DSM Brochure, And Claim 1 of the 446 Patent

42. Claim 1 of the 446 Patent claims a *suture* (Ex. 2 at 8:62-10:19). The 688 patent does not teach a suture.

43. Claim 1 of the 446 Patent claims certain yarns that are braided in "direct intertwining contact" (Ex. 2 at 8:67). The 688 patent also lacks a yarn from the claimed first set of fiber-forming materials yarns braided in "direct intertwining contact" with a yarn from the claimed second set of fiber-forming materials.

44. Dr. Mukherjee has opined that (i) the first-fiber forming material of claim 1 of the 446 Patent is fiber set 9 in the 688 patent; (ii) the claimed second-fiber forming material of claim 1 of the 446 patent is either fiber set 11 or 13 in the 688 patent; and (iii) the claimed direct intertwining contact of claim 1 of the 446 patent is the braiding of fiber set 9 with either fiber set 11 or 13 in the 688 patent (Mukherjee at 11-12). I disagree. Element 9 in the 688 patent is a straight fiber, while the elements 11 and 13 are helically wound around element 9 (Ex. 3 at Fig. 1 & 2; 3:65-4:14). Thus, element 9 is not mechanically interlocked with either element 11 or 13 and is not braided with either element 11 nor 13 "in direct intertwining contact," as claimed in the 446 Patent. For example, in a direct intertwining braided construction, one set of yarns is interlocked with the other, so that they are held within the braid by the other set of yarns (see Ex. 2 at 5:18-26). In contrast, in the 688 patent, fibers 9 are not interlocked with fibers 11 or 13.

45. There are also differences between claim 1 of the 446 patent and the 802 patent. Claim 1 of the 446 Patent recites a *heterogeneous braid* of two yarns, a *direct intertwining contact* braid of braided yarns, and *specific yarns* in the braid (Ex. 2 at 8:63-9:10). Although the 802 patent discloses a suture of certain copolymers, the 802 patent does *not* recite a heterogeneous braid of two yarns, a direct intertwining contact braid of yarns, nor the specific yarns claimed in the 446 patent in a braid. Rather, the 802 focuses on a new block copolymer structure and mentions general applications for it. There is no mention of braiding the claimed materials as braided in claim 1 of the 446 patent. Thus, although the 802 patent refers to a suture, it is missing most of the other claim elements.

46. Similarly, there are also differences between the invention of claim 1 of the 446 Patent and the DSM Brochure. Claim 1 of the 446 patent claims a heterogeneous braid (Ex. 2 at 8:63-9:10). The DSM brochure does not disclose or suggest a heterogeneous braid.

47. The 446 Patent claims a heterogeneous braid of PE with nylon, aramid, or PET (Ex. 2 at 8:63-10:19). The DSM brochure does not disclose or suggest using nylon, aramid, or PET with Dyneema at all, let alone in a suture, or in a heterogeneous braided suture wherein dissimilar yarns are in direct intertwining contact.

3. One of Ordinary Skill in the Art Would Not Have Been Motivated To Combine The 688 Patent And The 802 Patent At The Time Of The Invention To Form The Suture Of Claim 1 Of The 446 Patent

48. Dr. Mukherjee opines that one of skill in the art would have been motivated to combine the 688 and 802 patents in such a way so as to form the claimed invention (Mukherjee at 13). I disagree because there are significant differences between the 688

and 802 patents and the invention of claim 1 of the 446 patent. Further, there is no suggestion or teaching to modify them or combine them in such a way, so as to form the suture of claim 1 of the 446 patent.

49. There is no motivation to modify either the 802 or 688 patents in light of the teachings of the other to form the claimed invention.

50. One of ordinary skill in the art would not have not have been motivated to modify the 688 patent in light of the 802 patent to form the claimed invention because there are significant differences between the suture of claim 1 of the 446 patent and the 688 and 802 patents. Neither the 688 patent nor the 802 patent teaches a suture having a heterogeneous braid in direct intertwining contact. Further, neither teaches the materials claimed in the 446 patent braided in direct intertwining contact. Given these significant differences, one of ordinary skill in the art would not have been motivated to form the claimed invention from the 688 and 802 patents.

51. Dr. Mukherjee has opined that merely because the 802 patent discloses a block copolymer that can be used as a suture or in a ligament prosthesis, one of ordinary skill in the art would have been motivated to modify the tubular prosthesis of the 688 patent into the invention of claim 1 of the 446 patent. But the triaxial-braided fabric element of the 688 patent is braided on a triaxial braider. One of ordinary skill in the art at the time of the invention would not have been motivated to form a suture, as recited in claim 1 of the 446 Patent, based on the teachings of the 688 patent, because the claimed suture could not be made with a triaxial braider. Notably, a triaxial braider is generally used for larger woven tubular structures, not sutures. For example, the 688 patent examples 1 and 2 are hollow-tubular prostheses that have a circumference of about 21 and 19 mm

(Ex. 3 at 8:58-9:17). In contrast, sutures generally have a diameter on the order of less than 2 mm in diameter (See Ex. 11 at sec. 24) (a #2 suture is about 0.55 mm. in diameter). The structure taught by the 688 patent is simply too big for use as a suture.

52. I also disagree with Dr. Mukherjee's suggestion that the ligament prosthesis taught by the 688 patent could just be used as a suture. The structure taught by the 688 patent would have to be significantly modified to be a suture. Dr. Mukherjee provides no explanation of how one of ordinary skill in the art would have been motivated to change the triaxial-braided fabric disclosed in the 688 patent into a suture. Also, he provides no explanation of how the teachings of the 688 patent can be applied to the braiding equipment that is used for sutures to form a braid as claimed. Nor does the 802 patent provide any such explanation.

53. I further disagree with Dr. Mukherjee's opinion that just because the 802 patent references sutures and prosthesis, it provides motivation to change the ligament prosthesis of the 688 patent in such a way so as to form the suture of claim 1 of the 446 patent. The 688 patent teaches a ligament prosthesis that should be designed to have elastic behavior that matches the physical properties of the ligament being repaired (Ex. 3 at Fig. 5; 7:29-33). One of ordinary skill in the art at the time of the invention would have known that sutures generally are designed not to have elastic behavior that matches a ligament's physical properties. Sutures have a different function than the ligament disclosed in the 688 patent. Generally, sutures hold tissue together during the healing process. Therefore, sutures are typically designed to have some elasticity, but less elasticity than the ligament prosthesis taught by the 688 patent. Thus, between 1998-1992, one of ordinary skill in the art reading the 688 and 802 patents would have

recognized the differences between the tubular ligament prosthesis of the 688 patent and a suture, and would not have been motivated to modify the ligament prosthesis of the 688 patent into a suture, let alone into the suture recited in claim 1 of the 446 patent.

54. Dr. Mukherjee appears to say that there is motivation to combine the 688 and 802 patents because "the arts of the braided ligament prosthetics and braided sutures are so similar" (Mukherjee at 11) and because "teachings of the suture field were often applied to teachings of the prosthetics field, and vice versa" (Mukherjee at 12). In this instance, I disagree because the properties of the ligament prosthesis taught by the 688 patent and a suture are much different as described above. Further, the 688 ligament prosthesis is not suitable for use as a suture. Moreover, Dr. Mukherjee has not pointed to any motivation to combine the references in such a way so as to form the claimed invention. The mere fact that the 802 patent refers to both sutures and ligaments does not provide motivation to modify the 688 patent teachings in such a way, so as to form the suture of claim 1 of the 446 patent.

4. One of Ordinary Skill in the Art Would Not Have Been Motivated to Combine the 688 Patent with the DSM Brochure To Form The Suture of Claim 1 of the 446 Patent

55. Dr. Mukherjee has opined that one of ordinary skill in the art would have been motivated to combine the 688 patent and the DSM Brochure in such a way so as to form the claimed invention. I disagree because there are significant differences between the 688 patent and the DSM brochure and the suture of claim 1 of the 446 patent, and there is no suggestion or teaching in them to combine them in such a way so as to form the suture of claim 1 of the 446 patent.

56. There was no explicit motivation in either the 688 patent or the DSM brochure to modify either in light of the teachings of the other to form the claimed invention.

57. As explained above with reference to the combination of the 688 and 802 patents, there are significant differences between the 688 patent and claim 1 of the 446 patent. The 688 patent does not describe a suture. Nor does the 688 patent describe the claimed yarns of the 446 patent in direct intertwining contact. Also, the DSM brochure fails to describe any braiding operations, braiding constructions for a suture, heterogeneous braids, or the material claimed in the 446 patent. Thus, the DSM brochure does not cure the deficiencies in the teachings of the 688 patent. Because of the significant differences and a lack of any explanation in the 688 patent or the DSM brochure as to how to overcome these differences, there is no motivation to combine or modify them in such a way so as to form the suture of claim 1.

58. As described above, the ligament prosthesis taught by the 688 patent would have to be significantly modified in order to be formed into a suture, much less the suture of claim 1 of the 446 patent. The DSM brochure does not describe how to modify the triaxial braided ligament prosthesis of the 688 patent into a suture, much less the suture of claim 1 of the 446 patent. Therefore, for similar reasons as described above with reference to the 802 patent, there is no motivation to modify the ligament prosthesis of the 688 patent into suture.

59. Dr. Mukherjee cites to the DSM brochure for the mere proposition that it "recommends UHMWPE for both suture and ligaments together" (Mukherjee at 13). But this citation say nothing about how to modify the tubular prosthesis taught by the 688 patent to form the suture of claim 1 of the 446 patent. Thus, one of ordinary skill at the

time having the 688 patent and the DSM brochure would not have been motivated to modify the tubular prosthesis taught by the 688 into the suture claimed in the 446 patent.

5. One of Ordinary Skill in the Art Would Not Have Been Motivated to Combine the 688 Patent with the General State of the Art At The Time Of The Invention To Form The Suture of Claim 1 of the 446 Patent

60. Dr. Mukherjee also opines that the 446 Patent claims are obvious over the 688 patent when combined with the "general state of the art" (Mukherjee at 13). He appears to state that the general state of the art is that "teachings of the suture field were often applied to teachings of the prosthetics field, and vice versa" (Mukherjee at 12). But this does not provide motivation to modify the ligament prosthesis taught by the 688 patent to form the claimed suture because it does not describe how to (i) modify the triaxial tubular prosthesis of the 688 patent to form a suture; (ii) how to make a suture having the same structure as the triaxial tubular prosthesis of the 688 patent; or (iii) how to modify the triaxial tubular prosthesis of the 688 patent to have the limitations of the suture of claim 1 of the 446 Patent, including direct intertwining contact between the first and second fiber-forming materials.

6. Secondary Considerations of Non-obviousness

61. I also understand that commercial success of the claimed invention is indicative of the non-obviousness of the suture claimed in the 446 patent. I assume that the FiberWire products are covered by claims 1, 8, 9, and/or 12 of the 446 patent.

62. I have reviewed portions of Dr. Gering's report on damages.[4] The report shows the large number of sales of FiberWire products, and less sales of TevDek products (Gering Rpt. at 10-11). I understand that Tevdek is a braided polyester suture (Ex. 12 at 36:17-18; 36:25-37:1). Dr. Gering's report also shows that the FiberWire suture drove the sale of Arthrex's suture anchor products because the same Arthrex anchor was sold with FiberWire and Tevdek suture and the FiberWire products outsold the Tevdek products (Gering Rpt. at 7-13).

63. I also note that Mr. Grafton described Arthrex's Tevdek suture as not acceptable (Ex. 12 at 45-46), thereby indicating that the attributes of FiberWire relative to Tevdek have been a reason for the sales of its FiberWire products. For example, Mr. Grafton testified that Arthrex was having "issues from customers with the Tevdek suture being low tensile strength as compared to competitors' suture anchors with suture, primarily Ethicon" (Ex. 12 at 44:13-16). He further explained that surgeons, who were friendly to Arthrex, had broken Tevdek sutures when trying to tie knots (Ex. 12 at 44:18-45:9). According to Mr. Grafton, the solution to this commercial problem was braiding UHMW PE with PET in direct intertwining contact (Ex. 12 at 44:5-54:5). Thus, Mr. Grafton's experience with TevDek and FiberWire confirms that FiberWire has been successful due to its braid construction which is claimed in the 446 patent.

64. I have also reviewed ¶¶ 73-77 of Dr. Brookstein's report. In his report, he describes that FiberWire's benefits that are marketed by Arthrex are due to the features claimed in the 446 patent. Based on Dr. Brookstein's report, Mr. Grafton's testimony, and Dr. Gering's report, FiberWire's commercial success can be attributed to the suture

[4] I assume that Dr. Gering's and Dr. Brookstein's reports are true. I am not opining on the issues for which they are opining.

claimed in the 446 patent. Thus, FiberWire's commercially success reflects the non-obviousness of at least claims 1, 2, 8, 9, and 12 of the sutures claimed in the 446 patent.

65. I also understand that praise by others is indicative of non-obviousness. I understand that Mr. Grafton had tried making a braided suture with a braid having just UHMW PE, but failed because the UHMW PE was too lubricious (Ex. 12 at 53-54). After he was unsuccessful with making a suture from just UHMW PE, Mr. Grafton thought of the idea of braiding UHMW PE yarns with PET yarns in direct intertwining contact (Ex. 12 at 53). When he explained his idea to Dr. Burkhart, who I understand is a surgeon, Dr. Burkhart described the idea as "killer" (Ex. 12 at 54). But Mr. Grafton's idea was patented in claims 1, 2 and 8 of the 446 patent. Thus, Dr Burkhart's praise for the idea was really a recognition of the importance of the 446 patent and indicative of the non-obviousness of at least claims 1, 2, and 8 of the 446 patent.

7. Claims 1, 2, 8, 9, and 12 of the 446 Patent Are Not Obvious Over the 688 Patent In Light Of The References Cited by Dr. Mukherjee

66. Based on (i) the scope and teachings of the 688 patent, the 802 patent, the DSM brochure, and the general state of the art referred to by Dr. Mukherjee; (ii) the differences between claim 1 of the 446 patent and the art cited by Dr. Mukherjee; (iii) the level of ordinary skill in the art; and (iv) the secondary considerations of non-obviousness, claim 1 of the 446 patent is non-obvious.

67. Claims 2 and 12 of the 446 patent recite the additional limitation that the suture of claim 1 "is attached to a needle" (Ex. 2 at 9:11-12). Because claims 2 and 12 contain all of the limitations of claim 1 plus an additional limitation, they are non-obvious for the same reasons as claim 1.

68. Claim 8 of the 446 patent recites that the "second set of yarns is PET" (Ex. 2 at 10:7-8), but is otherwise the same as claim 1. In order to show the obviousness of claim 8, the references must suggest (or motivate one of ordinary skill in the art to form) a suture having all of the limitations of claim 1 and the claimed second yarn being PET, as opposed to Nylon, PET, or aramid as recited in claim 1. The art relied upon by Dr. Mukherjee does not disclose the claimed second yarn as being PET for the reasons set forth above with respect to claim 1. Accordingly, except for my opinions regarding Nylon and aramid, my opinions described above with reference to the 688 patent and the other references apply to claim 8.

69. Claim 9 of the 446 patent is also non-obvious for the same reasons as claims 1 and for additional reasons. Claim 9 of the 446 patent recites that "the volume fraction of the first set of yarns in the braided sheath and core ranges from about 20 to about 80 percent" (Ex. 2 at 10:9-11; 18-19). Dr. Mukherjee has pointed to nothing that discloses this limitation. Given this additional difference of claim 9 and the lack of any motivation to form a suture having this limitation, claim 9 is non-obvious for this additional reason.

C. Claims 1, 2, 8, 9, and 12 of The 446 Patent Are Not Anticipated By Chesterfield

70. Dr. Mukherjee opined that Chesterfield "discloses every limitation of the asserted claims" (Mukherjee at 14). I disagree. The 575 patent does not disclose many limitations of claims 1, 2, 8, 9, and 12 of the 446 Patent.

71. The 575 patent does not disclose to one of ordinary skill in the art a heterogeneous braid of the claimed yarns from the first-fiber forming materials with the second fiber-forming materials in direct intertwining contact. Further, the 575 patent does not teach a suture having a braid of PE (including UHMW PE) with PET, Nylon, or

aramid. I understand that in order for the 575 patent to anticipate the 446 patent claims, it must disclose every limitation of the 446 Patent claims (expressly or inherently) arranged in the same way as claimed in the 446 Patent claims. Because the 575 patent does not teach all of the limitations of the claimed invention arranged in the same way, it is my opinion that there is no anticipation.

72. In general, I disagree with Dr. Mukherjee because he picks and chooses different teachings of the 575 patent and combines them in a way that is not described in the 575 patent and then concludes that the 575 patent teaches the claimed invention. Basically, he forms the claimed invention by selecting teachings about a sternum closure device in the 575 patent and combining them with select teachings about a suture repair device in the 575 patent. But I disagree with his analysis because the 575 patent does not expressly or inherently describe the claimed invention. I address some of Dr. Mukherjee's specific points below.

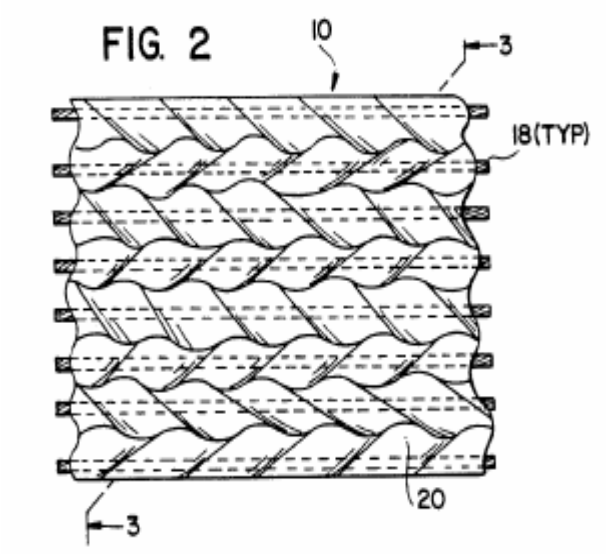
73. Dr. Mukherjee cites to column 3, lines 61-67, of Chesterfield as disclosing nylon or PET. I disagree. This citation does not refer to nylon or PET. In fact, column 3, lines 61-67, specifies that the material 20 is a "bioabsorbable polymeric material such as . . . polyester" (Ex. 6 at 3:63-67). Neither nylon nor PET are bioabsorable polyesters; they are non-absorbable materials. Thus, column 3, lines 61-67 is not a disclosure of either PET or nylon.

74. Dr. Mukherjee also cites to column, 3, lines 61-67, of Chesterfield as disclosing nylon or PET braided with UHMW PE in a *suture*. But I disagree. The 575 patent at column, 3, lines 61-67, describes that fibers 20 are used in the outer structure in the *sternum closure ribbon 10*, not a suture. Thus, this citation to col. 3, lines 61-67 does

not teach nylon or PET braided in a suture, much less braided in direct intertwining contact with UHMW PE.

75. Dr. Mukherjee cites the filler yarns 20 of the *sternum closure device* as being braided with the UHMW PE in the *spiroid braid* of Fig. 7. But the filler yarns 20 are from a *sternum closure device* (Figs. 2 and 4) and the UHMW PE (to which he cites) is from a *spiroid braid* (Fig. 7). Thus, they are not braided in direct intertwining contact as required by the 446 patent claims.

76. Further, Chesterfield does not teach a heterogeneous braid for the braided fibers 20 in the sternum closure device 10 (below). Rather, Chesterfield teaches that the braided fibers 20 are in a homogeneous woven structure (Ex. 6 at 3:61-4:1, 4:39-47).



Therefore, his citation to Chesterfield's sternum closure device does not disclose nylon, aramid, or PET braided in direct intertwining contact with PE in a suture, as claimed in the 446 Patent.

77. Again, Dr. Mukherjee piecemeals two materials from two different structures to describe the heterogeneous braided suture as claimed in the 446 Patent. Specifically,

Dr. Mukherjee takes the UHMW PE from the core of the *hollow braid* of Figs. 8 and 9 and matches it with either the (1) bioabsorbable polyester of the *sternum closure device* or (2) the material of the *spiroid braid* of Fig. 7. This picking and choosing of two different materials from two different structures does not teach a single suture construction having the claimed first and second fiber forming materials braided in direct intertwining contact as claimed in the 446 Patent.

78. Dr. Mukherjee also cites to column 7, lines 59-60, as disclosing a heterogeneous braid with direct intertwining contact where one of the yarns is PE (Mukherjee at 14-16). But column 7, lines 59-60 of Chesterfield only describes PE in the core. The PE referred to in column 7, lines 59-60, is not in the sheath, is not described as braided with another material, is not described as braided with the claimed second fiber-forming materials (nylon, aramid, or PET), and is not described as braided in direct intertwining contact with the claimed second fiber-forming materials.

79. Dr. Mukherjee also cites to claims 11 and 12 of the 575 patent as disclosing nylon and polyester respectively braided in direct intertwining contact with UHMW PE in a heterogeneous suture braid as claimed in the 446 patent. I disagree. Claims 11 and 12 of the 575 patent refer to second non-absorbable fibers as being formed from either nylon or polyester. But claims 11 and 12 of Chesterfield do not specify how the second fibers are braided with the claimed first fibers. For example, Chesterfield claims 11 and 12 do not recite that the first and second fibers are braided in direct intertwining contact, as opposed to a core-sheath arrangement (like that described in Chesterfield Figs. 8, reproduced below, & 9), with the first fiber materials only in the core and the second fiber materials only in the sheath.

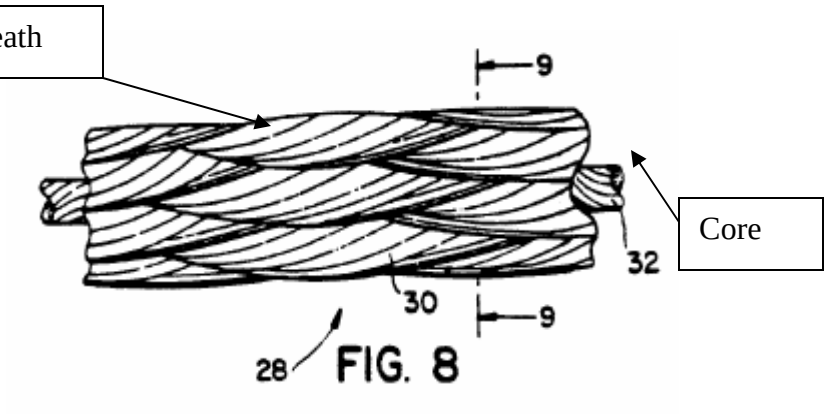


FIG. 8

80. Further, claims 11 and 12 recite a "method for repairing split portions of body tissue comprising looping a flexible elongated member about the body tissue..." (Ex. 6 at 8:29-38; 60-65). It is my opinion that this refers to a method of using the sternum closure device, not a suture, because a sternum closure goes "about" the margins of tissue (Ex. 6 at Fig. 1) while a suture goes through tissue. Thus, claims 11 and 12 do not refer to a suture and therefore cannot teach all the limitations of the claims of the 446 Patent.

81. Dr. Mukherjee also cites to Chesterfield at column 4, lines 9-23, as disclosing the second fiber forming materials (PET, nylon, or aramid) braided in direct intertwining contact with the first-fiber forming materials (Mukherjee at 16). But that portion of Chesterfield does not explicitly mention nylon, aramid, or PET. Although, that citation does state that "[a]ny number of combinations of bioabsorbable yarns, filamentary or otherwise, and/or non-absorbable, and high strength filaments are contemplated" (Ex. 6 at 4:20-24), it does not disclose how these materials are selected or arranged, such that a person of ordinary skill in the art would understand that nylon, aramid, or PET are necessarily disclosed and arranged as claimed in the 446 patent. For example, it does not disclose PET, Nylon, or aramid braided in direct intertwining contact with UHMW PE, as claimed in the 446 Patent.

82. I understand that for any claimed limitation to be inherently disclosed, it must necessarily be disclosed. I see no reason why PET, nylon, or aramid is necessarily disclosed as being braided with UHMW PE in direct intertwining contact in a suture as claimed in the 446 Patent based on Dr. Mukherjee's citation to column 4 of the 575 patent. For example, Dr. Mukherjee provides no explanation as to why one of ordinary skill in the art finds that this statement discloses selecting either PET, nylon, or aramid from the universe of possible yarns. Nor does he provide an explanation of why only one yarn would be picked to be braided with PE in direct intertwining contact when the 575 patent refers to "any combination" of the universe of yarns and does not specify any particular braiding arrangement.

83. I note that when Arthrex was prosecuting an application, which ultimately issued as the 234 patent, Arthrex represented to the Patent & Trademark Office that Chesterfield "does not disclose an example of a braided sheath that includes a blend of both UHMWPE and polyester" (Ex. 13 at DMI041091).

84. Thus, Arthrex's patent counsel agreed with me when it was prosecuting its own patent application.

85. Also, claim 9 of the 446 patent is not anticipated by Chesterfield for the additional reason that Chesterfield does not describe the limitation of claim 9 that the "volume fraction of the first set of yarns in the braided sheath and core ranges from about 20 to about 80 percent."

D. If The Claims Of The 446 Patent Are Construed To Mean That "PE" Includes UHMW PE, Then The 446 Patent Is Non-obvious Over Burgess And i) Cohan; ii) The DSM Brochure; And/Or iii) The Harpell Patents

86. My below opinions assume that the claims of the 446 Patent are construed to mean that "PE" includes UHMW PE.

1. It Is My Opinion That Claims 1, 2, 8, 9 and 12 of the 446 Patent Are Not Invalid For Obviousness Over Burgess In View Of Cohan

87. Dr. Mukherjee states that claims 1, 2, 8, and 12 of the 446 Patent are invalid as obviousness over Burgess in view of Cohan. I disagree. Below I discuss the teachings of Burgess and Cohan to one of ordinary skill in the art between 1988 and 1992.

a) The Scope And Content Of Burgess

88. Burgess discloses fishing lines (Ex. 7 at 1), not suture or medical devices. Burgess discusses certain desirable properties of a fishing line, but does not mention certain suture properties, such as knot security or knot strength (Ex. 7 at 1). Burgess does state that fishing lines "require… non-stretchability" (Ex. 7 at 1). Burgess states that "non-stretchability" is a fishing line requirement, not a preference (Ex. 7 at 1).

89. Burgess further discloses a fishing line that should have a "braided construction" (Ex. 7 at 1). Burgess discloses that some filaments are of "high tensile polythene thread" and other filaments are "polyester and/or nylon" (Ex. 7 at 1). But Burgess does not disclose what kind of "braided construction" he envisioned, how to construct the braid which he references, nor how to use the materials in the "braided construction" he references. For example, Burgess does not disclose whether the polythene thread should be in the core, whether it should be in the sheath alone, or in the sheath with another material. Nor does Burgess disclose whether the polyester and/or nylon alone

should be in the core, whether it should be in the sheath alone, or in the sheath with another material. At no point does Burgess state that the polythene can be in a sheath with another material such as nylon or polyester.

90. In fact, the Burgess disclosure is at most two double-spaced pages. Burgess has no drawings; Burgess provides no working detail or explanation whatever of the braided fishing-line construction which he references. Nor does he provide any description of how to make the "braided construction" to which he refers or the type of equipment that should be used to fabricate the "braided construction" for a fishing line.

91. Burgess discloses the use of high molecular weight polythene in a fishing line. However, one of ordinary skill in the art would know that high molecular weight polythene is a lubricious material with poor knot security and knot tie down characteristics. Burgess does not disclose how to overcome these characteristics of high molecular weight polythene. Notably, Mr. Grafton, former Arthrex employee and developer of FiberWire, also stated that UHMW PE was typically used for fishing line and did not have acceptable knot tie down characteristics for use in sutures (Ex. 14 at 1:14-20). Mr. Grafton also stated that the poor knot slippage of UHMW PE was due to its lubricity (Ex. 12 at 53). Thus, Burgess discloses high molecular weight polythene, which is known to be a lubricous material, but does not describe how to construct an acceptable suture with UHMW PE.

92. I disagree with Dr. Mukherjee about the scope and content of Burgess. Dr. Mukherjee states that "the Burgess application discloses every limitation of claim 1 of the '446 patent . . . except that Burgess is not a sterilized suture" (Mukherjee at 17). But Dr. Mukherjee does not provide any analysis as to where the claimed limitations are

found in Burgess. Nor does he explain why Burgess necessarily teaches the braid claimed in the 446 patent, as opposed to some other braid construction. Thus, I disagree with his reading of Burgess.

93. Dr. Mukherjee uses the prosecution history of the 446 patent to support his reading of Burgess. I disagree that the prosecution history supports his analysis. Dr. Mukherjee cites to the Examiner's statement that "Burgess discloses a fishing line of braided construction comprising filaments of polyethylene and filaments of polyester or nylon," and suggests that the Examiner stated that the "braided construction" of Burgess was the same as the claimed "heterogeneous braid" of yarns in "direct intertwining contact." But the Examiner never said this. Notably, the Examiner never stated that Burgess discloses the claimed "heterogeneous braid' of yarns in "direct intertwining contact." Rather, the Examiner only stated that Burgess disclosed a "braided construction," not any specific braided construction, and then concluded it would have been obvious in light of Burgess to form the claimed invention of then pending claims 21-24. Thus, contrary to Dr. Mukherjee's suggestion, the Examiner never stated that Burgess discloses a heterogeneous braid of UHMW PE and Polyester or nylon in "direct intertwining contact" as claimed in the 446 patent.

b) The Scope And Content Of Cohan

94. Cohan discusses the use of an ultra strong polyethylene fiber in an ophthalmic suture. According to Cohan, the "polyethylene fibers are monofilaments with a ribbon shape." It also describes three monofilaments made from nylon, polypropylene, and polyester. The Cohan article discusses testing each of these monofilaments. The testing results are summarized in Figs. 2-4 and Tables 1-3. Figure 2 shows that a continuous filament of polyethylene has a greater tensile strength at break than the

other materials in the figure and also breaks at a significantly lower elongation. Figure 3 compares the knot pull strength of four fibers and shows that the knot pull strength of PE is higher than the others. Figure 4 describes the results of knot holding strength testing and shows that when comparing the four materials using a knot sequence commonly used in surgery, PE fails at a lower value than the other materials. According to Figure 4, the knot holding strength of PE is lower for certain knot configurations because the PE slips, whereas each of the other three materials break at a higher strength value for these knot configurations.

95. Table 2 of Cohan summarizes knot holding strength for different knot configurations and for four materials. According to Table 2, when the knot configuration was 2=2, PE did not register a value because the knot holding strength was too low (the knot slipped) whereas each of the other three materials reached their knot holding strength without slipping. At the 3=2=1 and 4=1=1 configurations, the PE showed a lower knot holding strength (*e.g.* 0.35 GPa compared to 0.45, 0.60 & 0.55 at configuration 4=1=1), than the other three materials because, again, the PE was failing by slipping. This knot slippage is not desirable because it means that a knot will not hold. The authors noted that when they tested the PE with more complex (4=4 & 4=4=4) knots, the PE still slipped at 4=4. The PE did not reach its final knot holding strength until a 4=4=4 knot was used. This testing shows to one or ordinary skill in the art between 1988 and 1992 that PE monofilament did not have the knot holding strength of other commonly used monofilaments at the same knot configuration. Also, one of ordinary skill in the art would have known that minimizing the number of knots used to secure a suture in surgery was an important characteristic in suture development.

Therefore, one of ordinary skill in the art would have recognized that Cohan teaches away from using UHMW PE in a suture.

96. Cohan also describes clinical use of the PE monofilament suture. The article states that the PE suture spontaneously untied and at a rate more common than the other materials. The authors explained that this untying was a result of the high flexibility and low friction of the PE. According to the authors, two of the PE fibers acted like “tracks” allowing the third fiber to “slip.” The poor knot tying properties of these UHMW PE monofilaments are a property of the PE itself.

97. Also, Cohan describes the solution for PE’s lower knot holding strength was to tie more complex knots. Cohan does not mention or suggest forming a heterogeneous braid with PE to correct the problem. Thus, one of ordinary skill in the art would have recognized that Cohan teaches away from braiding UHMW PE in a suture.

98. Cohan shows Scanning Electron Micrographs (SEM) of the PE fibers. The SEM’s show lateral connections between the fibrila. The authors also noted in their clinical experience “the occasionally unraveling of microfilaments from the [PE] fiber, sometimes causing irritation until they were removed.” The authors do not explain the cause of the unraveling, or that the possible cause is the fibrila shown in Fig. 1. Further, the authors posit that the use of “gel-spinning” to synthesize the fibers may eliminate the unraveling. But they offer this only as a hypothesis not a proven solution. Because of this recognized, but unsolved problem, one of ordinary skill in the art between 1988 and 1992 would not have been motivated to use UHMW PE in sutures.

99. Cohan states that it was trying to design a suture that was stronger than multifilament silk suture but still has the handling properties of silk. The solution provided by the article is a monofilament PE that requires more complex knots.

100. Dr. Mukherjee makes several statements with respect to Cohan with which I disagree. For example, he states that Cohan teaches a suitable suture made of UHMW PE, and that it is superior. He misinterprets the test results in Table 2. He states that the suture made of UHMW PE had superior knot strength and knot security when compared to the other materials. But Table 2 of Cohan shows that PE had less knot holding strength and less knot security when using comparable knot configurations. In fact, the authors noted that the PE constructs had less knot security because they slipped and failed using certain commonly employed knot configurations.

101. I also disagree with Dr. Mukherjee's statement that Cohan describes a "superior" UMMW PE suture because Cohan's solution to the knot holding strength of UHMW PE was to tie more complex knots. One of ordinary skill in art would recognize this solution was not commercially acceptable to surgeons. A suture that requires a surgeon to tie more complex knots is simply not a "superior" suture.

102. I further disagree with Dr. Mukherjee's statement that Cohan describes a "superior" UHMW PE suture because the authors noted that PE spontaneously untied at a greater rate than the other materials during clinical studies. The unraveled PE led to irritation. Although Cohan posits the hypothesis that "gel-spinning" may eliminate the unraveling, this is an unproven solution to the problem. Thus, given these unresolved issues recognized by Cohan, I do not understand how Dr. Mukherjee opines that the monofilament PE suture of Cohan is a superior suture with superior knot security.

c) The Differences Between Burgess And Cohan And Claim 1 of the 446 Patent Are Significant

103. There are many differences between claim 1 of the 446 patent and the combination of Burgess and Cohan. These differences indicate the non-obviousness of claim 1 of the 446 patent.

104. Claim 1 of the 446 Patent claims a suture. Burgess only describes a fishing line.

105. Claim 1 of the 446 Patent claims a heterogeneous braid where at least one set of yarns from the first group is in direct intertwining contact with at least one yarn from the second group. Burgess does not teach this. In fact, Burgess is entirely silent on the construction of the fishing line or its method of assembly. Thus, Burgess does not teach the braid recited in claim 1 of the 446 Patent.

106. Also, because Burgess does not describe the braided construction he references and does not describe how to make it, Burgess does not enable one skilled in the art between 1988 and 1992 to make and use a suture of claim 1 of the 446 Patent. I do not understand how Dr. Mukherjee considers Burgess to be detailed enough to teach one of ordinary skill in the art in 1992 how to make and use the claimed heterogeneous braid of the 446 Patent, and at the same time opine that the 446 Patent, which is much more detailed than Burgess, does not enable one of skill in the art to make and use the invention claimed in the 446 Patent. Burgess simply does not describe any type of braiding construction, braiding equipment or any braid manufacturing or processing.

107. Likewise, Cohan does not teach the invention of claim 1 of the 446 Patent. Nor does Cohan fill in the gaps left by Burgess. Cohan does not teach a heterogeneous braided suture. Further, the Cohan article does not teach the materials recited in claim

1 of the 446 Patent, where at least one material from the claimed first-fiber group is in direct intertwining contact with a yarn from the claimed second-fiber group.

108. I note here that I disagree with Dr. Mukherjee's opinion that Cohan somehow demonstrates that Mr. Goodwin was incorrect in his response to the patent office when discussing Burgess (Mukherjee at 18). First, Dr. Mukherjee inaccurately paraphrases Mr. Goodwin's statements to the Patent Office. Dr. Mukherjee incorrectly characterizes Mr. Goodwin's statements as "if one were to make a product with high tensile polythene . . . it would be 'unsuitable for use as sutures'" (Mukherjee at 18). Mr. Goodwin never said this. Rather, he said that a medical designer following the teachings of Burgess on how to construct a fishing line with different design criteria than suture would inevitably design an unacceptable suture.

109. Secondly, contrary to Dr. Mukherjee's statements, Cohan shows that Mr. Goodwin was correct. Cohan describes that UHMW PE has poor knot holding strength, which means it is has poor knot strength and poor knot security. Thus, Mr. Goodwin's statements were accurate that knot security and knot strength are a concern and Burgess does not discuss how to address these issues. This is confirmed by Arthrex's 234 patent which explains that fishing line having UHMW PE "does not have acceptable knot tie down characteristics for use in surgical applications" (Ex. 14 at 1:13-20).

d) One of Ordinary Skill in the Art Would Not Have Been Motivated to Combine Burgess with Cohan to Form the Claimed Invention

110. One of ordinary skill in the art would not have been motivated to combine Burgess and Cohan between 1988 and 1992 to form the suture of claim 1 of the 446 Patent. There is no motivation in either Burgess or Cohan to combine them. Also, as

discussed below there is no motivation based on their teachings or the level of skill in the art for several reasons.

111. First, because of the significant differences between Burgess and Cohan and claim 1 of the 446 patent, one of ordinary skill in the art would not have been motivated between 1988 and 1992 to modify Burgess to form the claimed invention. For example, neither describes the claimed heterogeneous suture braid of claim 1 of the 446 Patent, and there is no motivation or suggestion to combine the references to form the claimed braided suture.

112. Second, because Burgess does not describe knot security or knot strength, one of ordinary skill in the art between 1988 and 1992 would not have been motivated to use the teachings of Burgess to make a suture. Knot security and knot strength are two important suture properties. Therefore, Burgess' discussion of different requirements for fishing line and failure to mention knot strength or knot security would cause one of ordinary skill in the art not to be motivated to use Burgess' teachings in designing a suture.

113. Third, Cohan recognizes that monofilament PE has lower knot holding strength and posits overcoming this problem by tying more complex knots. Burgess says nothing about knot holding strength or how to solve the issues raised by Cohan. Thus, one of ordinary skill in the art would not have been motivated to combine Burgess and Cohan to form the claimed invention because he would have focused on trying to resolve the knot holding strength issues raised by Cohan by tying different knots.

114. Fourth, Cohan teaches that monofilament UHMW PE had disadvantages including lower knot holding strength, requiring more complex knots, spontaneous

untying, and unraveling, leading to irritation. Given these problems with the UHMW PE monofilament in Cohan, one of ordinary skill in the art having read Cohan between 1988 and 1992 would not have been motivated to further pursue using UHMW PE without first solving these issues.

115. Fifth, even assuming that one of ordinary skill in the art would have been motivated to pursue the teachings of Cohan, Cohan teaches away from braiding. Cohan teaches trying to design a suture that was stronger than multifilament silk suture, but still had silk's handling properties by tying more complex knots. One of ordinary skill in the art between 1988 and 1992, who had read Cohan, would have focused on monofilaments, tying different types of knots, and eliminating unraveling, not braiding.

116. I have read Dr. Mukherjee's report and Dr. Mukherjee does not specify any motivation for combining the Burgess reference with the Cohan article. He also ignores the differences between the monofilament described in Cohan and the claimed invention of the 446 Patent and the problems noted by Cohan with UHMW PE. Thus, I disagree with his opinion.

117. I note that Dr. Mukherjee states that "it would have been obvious to a person of ordinary skill in the art, in February 1992, to use a heterogeneous braid, such as that disclosed in the Burgess application, for a suture" (Mukherjee at 18). I disagree for the reasons set forth above, but note that the general problem with this statement is that Burgess does not disclose any specific braid construction. Thus, one of ordinary skill in the art reading Burgess in 1992 would not have been able to just simply use a braid disclosed by Burgess as a suture, as Dr. Mukherjee suggests.

e) The Combination of Burgess & Cohan is Cumulative to References The Examiner Considered

118. Dr. Mukherjee relies on Burgess for his obviousness opinions. But Burgess was considered by the Examiner. Dr. Mukherjee's obviousness opinions with respect to Burgess appear to be based on the incorrect premise that the Examiner was not aware of a reference showing that UHMW PE could be used in a suture, and if he was, he would have combined it with Burgess to reject the 446 patent application claims. But the Examiner already considered a reference that explicitly discloses using UHMW PE in a suture (Ex. 15 at PCT application WO 86/00020 at DMI000150-179, *e.g.* Abstract and p. 8). Therefore, the Examiner considered Burgess and a reference disclosing the use of UHMW PE in a suture (Ex. 17 at DMI000596). Consequently, to the extent that Dr. Mukherjee's obviousness opinions rely on Burgess and other references showing UHMW PE in sutures, his opinions are based on information already considered and rejected by the Examiner. Thus, the Examiner's issuance of the 446 patent over these references confirms my opinions of non-obviousness.

f) Secondary Considerations of Non-obviousness

119. As explained above, the inventions of claims 1, 2, 8, 9, and 12 of the 446 patent have been commercially successful and have been praised by Arthrex. This indicates their non-obviousness.

g) Claims 1, 2, 8, 9, and 12 of the 446 Patent Are Not Obvious Over Burgess in light of Cohan

120. Based on (i) the scope and teachings of Burgess and Cohan; (ii) the differences between claim 1 of the 446 patent and Burgess and Cohan; (iii) the level of ordinary skill in the art; (iv) the secondary considerations of non-obviousness; and (v) Burgess and

Cohan being cumulative to the information considered by the Examiner, claim 1 of the 446 patent is non-obvious.

121. Claims 2 and 12 of the 446 patent recite the additional limitation that the suture of claim 1 "is attached to a needle" (Ex. 2 at 9:11-12). Because claims 2 and 12 contain all of the limitations of claim 1 plus an additional limitation, they are non-obvious for the same reasons as claim 1.

122. Claim 8 of the 446 patent recites that the "second set of yarns is PET" (Ex. 2 at 10:7-8), but is otherwise the same as claim 1. In order to show the obviousness of claim 8, the references must show a suture having all of the limitations of claim 1 and the claimed second yarn being PET, as opposed to Nylon, PET, or aramid as recited in claim 1. The art relied upon by Dr. Mukherjee does not disclose the claimed second yarn as being PET for the reasons set forth above with respect to claim 1. Accordingly, except for my opinions regarding Nylon and aramid, my opinions described above with reference to Burgess and Cohan apply to claim 8.

123. Claim 9 of the 446 patent is also non-obvious for the same reasons as claim 1 and for additional reasons. Claim 9 of the 446 patent recites that "the volume fraction of the first set of yarns in the braided sheath and core ranges from about 20 to about 80 percent" (Ex. 2 at 10:9-11). Dr. Mukherjee has pointed to nothing that discloses this limitation. Given this additional difference of claim 9 and the lack of any motivation to form a suture having this limitation, claim 9 is non-obvious for this additional reason.

2. It Is My Opinion That Claims 1, 2, 8, 9, and 12 of the 446 Patent Are Not Obvious Over Burgess & The DSM Brochure

124. Claims 1, 2, 8, 9, and 12 of the 446 patent are not obvious over Burgess in light of the DSM brochure. I have described the scope and content of Burgess and the DSM

brochure above. Also, I have described the differences between Burgess and the DSM brochure and the sutures of claims 1, 2, 8, 9, and 12 above. Those discussions apply here as well.

a) One of Ordinary Skill in the Art Would Not Have Been Motivated to Combine Burgess with the DSM Brochure to Form Claim 1 of the 446 Patent

125. One of ordinary skill in the art from 1988-1992 would not have been motivated to combine Burgess and the DSM brochure to form the claimed invention of the 446 Patent for many reasons. There is no motivation to combine them in such a way so as to form the claimed suture of the 446 patent.

126. First, because of the significant differences between the invention claimed in the 446 patent and Burgess and the DSM brochure, one of ordinary skill in the art between 1988 and 1992 would not have been motivated to combine them to form the claimed invention. For example, because neither describes a heterogeneous braid of yarns in direct intertwining contact, as claimed in the 446 Patent, there is no motivation or suggestion to combine the references to form the claimed heterogeneous braid. Burgess does not describe how to combine the polyester and/or nylon with UHMW PE. The DSM brochure does not describe combining yarns at all or how to construct any type of suture. Thus, because of the significant differences between the invention claimed in the 446 patent and these references and the lack of any guidance as to how or why to make a braid, there is no motivation or suggestion as to how to combine the UHMW PE with nylon and/or polyester to form a heterogeneous braid in direct intertwining contact as claimed in the 446 Patent.

127. Second, because Burgess does not describe knot security or knot strength and the DSM brochure touts the high knot strength of certain Dyneema fibers, one of

ordinary skill in the art between 1988 and 1992 would not have been motivated to use the teachings of the DSM brochure with the teachings of Burgess. One of ordinary skill in the art in 1992 would have been motivated to explore using just the UHMW PE fibers taught by the Dyneema brochure to take advantage of the touted knot strength. There is no discussion in either reference of how braiding affects knot strength. In my opinion, one of ordinary skill in the art would not have attempted to braid UHMW PE with nylon or PET based on these references because the resulting effect on knot strength was not known.

128. Third, one of ordinary skill in the art would not have been motivated to combine the DSM brochure and Burgess to form the claimed suture of the 446 patent because he would have known that the UHMW PE disclosed in the DSM brochure was lubricous and therefore would not provide good knot security. Neither the DSM brochure nor Burgess discuss how to address UHMW PE's lubricity and form a suitable suture. Thus, absent a teaching addressing this issue, one of ordinary skill in the art would not have been motivated to combine Burgess and the DSM brochure to arrive at the claimed invention.

129. I note that Dr. Mukherjee does not provide any motivation or suggestion to combine Burgess and the DSM brochure to form the claimed invention. Dr. Mukherjee opines that one of ordinary skill in the art in 1992 would have "been motivated to take the recommendation of the DSM brochure to use Dyneema in a suture application and to combine it in a braided suture with polyester/and or nylon, as in Burgess." But Burgess is not a "suture application." Therefore, even if one of ordinary skill in the art would have been motivated to use the Dyneema described in the DSM brochure in

"suture application," it would not be with Burgess. Further, even if one was motivated to use the Dyneema with the teachings of Burgess, Burgess does not describe any braid construction. Therefore, there is no motivation or suggestion to form the claimed invention.

b) The Combination of Burgess & the DSM Brochure is Cumulative to References The Examiner Considered

130. Dr. Mukherjee's obviousness opinions with respect to Burgess and the DSM Brochure appear to be based on the incorrect premise that the Examiner was not aware of a reference showing that UHMW PE could be used in a suture, and if he was, he would have combined it with Burgess to reject the 446 patent application. But, as described above with reference to Cohan, the Examiner already considered a reference that explicitly discloses using UHMW PE in a suture (Ex. 15 at PCT application WO 86/00020 at DMI000150-179, *e.g.* Abstract and p. 8). Thus, Burgess and the DSM Brochure are cumulative to the references considered by the Examiner, and the Examiner's issuance of the 446 patent over these references confirms my opinions of non-obviousness.

c) Secondary Considerations of Non-obviousness

131. As explained above, the inventions of claims 1, 2, 8, 9, and 12 of the 446 patent are non-obvious and have been praised by Arthrex. This indicative of their non-obviousness.

d) Claims 1, 2, 8, 9, and 12 of the 446 Patent Are Not Obvious Over Burgess & the DSM Brochure

132. Based on (i) the scope and teachings of Burgess and the DSM brochure; (ii) the differences between claim 1 of the 446 patent and Burgess and the DSM brochure; (iii) the level of ordinary skill in the art; (iv) the secondary considerations of non-

obviousness; (v) and Burgess and the DSM brochure being cumulative to the information considered by the Examiner, claim 1 of the 446 patent is non-obvious.

133. Claims 2 and 12 of the 446 patent recite the additional limitation that the suture of claim 1 "is attached to a needle" (Ex. 2 at 9:11-12). Thus, claims 2 and 12 of the 446 patent are non-obvious for the same reasons as claim 1 of the 446 patent. Claim 8 of the 446 patent recites that the "second set of yarns is PET" (Ex. 2 at 10:7-8). As described above, neither Burgess not the DSM brochure disclose PET braided as claimed. Thus, with this exception that claim 1 recites that the second fiber forming material could be nylon, aramid, or PET, my opinions described above with reference to Burgess and the DSM brochure apply to claim 8 as well, and it is non-obvious.

134. Claim 9 of the 446 patent are also non-obvious for the same reasons as claims 1 and for additional reasons. Claim 9 of the 446 patent recites that "the volume fraction of the first set of yarns in the braided sheath and core ranges from about 20 to about 80 percent" (Ex. 2 at 10:9-11). Dr. Mukherjee has pointed to nothing that discloses this limitation. Given this additional difference of claim 9 and the lack of any motivation to form a suture having this limitation, claim 9 is for this additional reason non-obvious.

3. Claims 1, 2, 8, 9, and 12 of the 446 Patent Are not invalid For Obviousness Over Burgess and the Harpell Patents

a) The Scope and Content of Burgess & the Harpell patents

135. The scope and content of Burgess is discussed above. Below, I discuss the teachings of the Harpell patents to one of ordinary skill between 1988 and 1992. Because Dr. Mukherjee has not differentiated between the Harpell patents and they appear to be substantially the same, I refer to the 392 Harpell patent for convenience.

136. The Harpell patents teach that extended chain polyolefin fibers, such as those formed from polyethylene and polypropylene (Ex. 9 at 1:8-9), have two disadvantages. First, the Harpell patents describe extended chain polyolefin fibers as having "low transverse strengths, with a corresponding tendency of the fibers to fibrillate especially when subjected to abrasion or self-abrasion, particularly when twisted or processed into a fabric" (Ex. 9 at 1:29-32). Second, the Harpell patents state that extended chain polyolefin fibers "have poor adhesion to most matrix materials" (Ex. 9 at 1:38). According to the Harpell patents, these disadvantages "limit the usefulness of these fibers in composite structures" (Ex. 9 at 1:39).

137. In order to overcome these disadvantageous, the Harpell patent teaches coating the extended chain polyethylene or polypropylene fibers with a "polyethylene, polypropylene, ethylene copolymer or propylene copolymer" (Ex. 9 at 1:43-45). The Harpell patents teach that coating the fibers "reduces the tendency of the fibers to fibrillate, increases their transverse strength, enables the fibers to be used in composite structures alone or with a variety of matrix materials and achieves these results without any significant loss of the tenacity and modulus values for the fiber alone (Ex. 9 at 1:46-51).

b) The Difference Between Burgess & The Harpell Patents And Claim 1 of the 446 Patent

138. The differences between claim 1 of the 446 patent and Burgess were discussed above. The Harpell patents are also different than claim 1 of the 446 patent. Claim 1 of the 446 patent claims a heterogeneous braid of yarns in direct intertwining contact. The Harpell patents do not disclose a heterogeneous braided suture, let alone direct intertwining contact of two dissimilar yarns. Claim 1 of the 446 patent claims a

heterogeneous braid of certain materials. The Harpell patents do not disclose a braid having the claimed first and second fiber-forming yarns. Thus, both the Burgess and Harpell references do not contain numerous features recited in the claims of the 446 patent.

c) One of Ordinary Skill in the Art Would Not Have Been Motivated to Combine Burgess with the Harpell patents to Form Claim 1 of the 446 Patent

139. There is no motivation or suggestion to modify either Burgess or the Harpell patents in such a way so as to form the suture of claim 1 of the 446 patent.

140. Given the significant differences between the references and claim 1 of the 446 Patent, one of ordinary skill in the art would not have been motivated to combine the references to form the claimed suture. Neither Burgess nor the Harpell patents describe how to braid the materials in direct intertwining contact as recited in claim 1 of the 446 patent. The Burgess reference offers no specificity about the construction of the braid other than to use the term “braid.” This hollow disclosure does not motivate one of ordinary skill in the art to use it in combination with the Harpell patents. Consequently, there is nothing in these references to teach one of ordinary skill in the art to make the invention of claim 1 of the 446 patent.

141. One of ordinary skill in the art would not have been motivated to combine the Harpell patents and Burgess for the additional reason that neither of these references describe knot security or knot strength. Knot security and knot strength are two characteristics important to a suture developer. Therefore, because there is no mention of these important characteristics, one of ordinary skill in the art would not have been motivation to use them together to improve suture properties.

142. Also, one of ordinary skill in the art would not have been motivated to combine Burgess and the Harpell patents because the Harpell patents describe coating fibers to reduce fibrillation. The Harpell patents describe certain fibers and coating them in the range of 0.1% to 200% by weight of fiber in order to reduce fibrillation (Ex. 10 at 4:40-42). With respect to suture applications, the Harpell patents disclose that a "preferred coating amount is between about 10 and about 50%, by weight of fiber" (Ex. 10 at 4:44-45). Therefore, rather than forming the claimed suture, one of ordinary skill in the art having read the Harpell patents between 1988-1992 would have been motivated to apply different coatings, in various amounts, and in different ways, to different UHMW PE or extended chain polypropylene fibers to determine whether the fibrillations could be reduced, not to form braided heterogeneous sutures.

d) The Combination of Burgess & the Harpell Patents is Cumulative to References The Examiner Considered

143. Dr. Mukherjee's obviousness opinions with respect to Burgess and the Harpell patents appear to be based on the incorrect premise that the Examiner was not aware of a reference showing that UHMW PE could be used in a suture, and if he was, he would have combined it with Burgess to reject the 446 patent application. But, as described above with reference to Cohan, the Examiner already considered a reference that explicitly discloses using UHMW PE in a suture (Ex. 15 at PCT application WO 86/00020 at DMI000150-179, *e.g.* Abstract and p. 8). Thus, Burgess and the Harpell patents are cumulative to the references considered by the Examiner, and the Examiner's issuance of the 446 patent over these references confirms my opinions of non-obviousness.

e) Secondary Considerations of Non-obviousness

144. As explained above, the inventions of claims 1, 2, 8, 9, and 12 of the 446 patent are non-obvious and have been praised by Arthrex. This indicates their non-obviousness.

f) Claims 1, 2, 8, 9, and 12 of the 446 Patent Are Not Obvious Over Burgess & the Harpell Patents

145. Based on (i) the scope and teachings of Burgess and the Harpell patents; (ii) the differences between claim 1 of the 446 patent and Burgess and the Harpell patents; (iii) the level of ordinary skill in the art; (iv) the secondary considerations of non-obviousness; and (v) Burgess and the Harpell patents being cumulative to the information considered by the Examiner, claim 1 of the 446 patent is non-obviousness.

146. Claims 2 and 12 of the 446 patent recite the additional limitation that the suture of claim 1 "is attached to a needle" (Ex. 2 at 9:11-12). Thus, claims 2 and 12 of the 446 patent are non-obvious for the same reasons as claim 1 of the 446 patent.

147. Claim 8 of the 446 patent recites that the "second set of yarns is PET" (Ex. 2 at 10:7-8). As described above, neither Burgess not the Harpell patents disclose PET braided as claimed. Thus, with this exception that claim 1 recites that the second fiber forming material could be nylon, aramid, or PET, my opinions described above with reference to Burgess and the Harpell patents apply to claim 8 as well, and it is non-obvious.

148. Claim 9 of the 446 patent is also non-obvious for the same reasons as claim 1 and for additional reasons. Claim 9 of the 446 patent recites that "the volume fraction of the first set of yarns in the braided sheath and core ranges from about 20 to about 80 percent" (Ex. 2 at 10:9-11). Dr. Mukherjee has pointed to nothing that discloses this

limitation. Given this additional difference of claim 9 and the lack of any motivation to form a suture having this limitation, claim 9 is for this additional reason non-obvious.

VII. It Is My Opinion That All of the Claims of the 446 Patent Are Not Invalid For Failing To Satisfy The Written Description & Enablement Requirements

A. The 446 Patent is Not Invalid for Failing to Satisfy the Written Description Standard

149. Dr. Mukherjee opines that all of the claims of the 446 Patent are invalid for failing to satisfy the written description standard. According to Dr. Mukherjee, the 446 Patent "does not reasonably convey to one of ordinary skill in the art that the inventors had possession of UHMWPE" (Mukherjee at 22). Since this is the only issue that Dr. Mukherjee has raised with respect to written description, it is the only one that I address. I disagree with his opinion. The 446 Patent does reasonably convey to one of skill in the art that the inventors had possession of the claimed suture with UHMW PE as the first-fiber forming material.

150. My opinion is supported by the 446 Patent's text. The 446 Patent specifically claims "PE." Further, the 446 Patent expressly describes "polyethylene (PE)" (Ex. 2 at 4:27,30). One of skill in the art would have known that "PE" means "polyethylene" and means all polymers made from ethylene. PE is the generic name for all types of PE, including UHMW PE. In 1987, the Encyclopedia of Polymer Science and Engineering 2nd edition volume 10 recognized polyethylene as the "common (source-based)" name for all polymers made from ethylene (Ex. 18). Further, the IUPAC officially recognized that PE is the accepted abbreviation for all types of PE (Ex. 19). Thus, one of skill in the art would have known that "PE" or "polyethylene" as used in the 446 Patent means all polymers from ethylene including UHMW PE.

151. The 446 Patent's description of PE is consistent with all types of PE. The 446 Patent states that in a preferred embodiment the first set of yarns act as lubricating yarns (Ex. 2 at 4:11-12). PE including UHMW PE is a lubricious yarn (Ex. 12 at 52-53). Cohan shows that one of skill in the art would have known that UHMW PE is a lubricious material because the UHMW PE used in the Cohan article slipped and required complex knot configurations in order to evaluate the material's knot hold strength. Also, the 446 Patent states that the first set of yarns may be derived from "non-absorbable polymers." PE including UHMW PE is a non-absorbable polymer. The 446 Patent also describes the first set of yarns as being made from fiber forming materials (Ex. 2 at 4:30-32). PE including UHMW PE is a fiber forming material. Therefore, the 446 Patent's description of PE is consistent with the meaning of PE and does not exclude UHMW PE.

152. My opinion that "PE" as used in the 446 Patent includes UHMW PE is supported by Arthrex's use of the term "polyethylene." I note that Arthrex described the UHMW PE used in FiberWire and other sutures as "polyethylene" without specifically calling out that it is UHMW PE (Ex. 20 at ARM002188-89; Ex. 21 at ARM02184-87; Ex. 22 at DMI Ex. 343). Also, I note that Cohan refers to ultrastrong polyethylene in the first instance but thereafter Cohan uses the terms ultrastrong polyethylene and polyethylene interchangeably to describe the suture materials. Further, my opinion that one of skill in the art would understand PE to include UHMW PE is confirmed by the DSM brochure. The brochure teaches that "polyethylene" properties cover the range from 1 N/tex specific strength and 25 N/tex specific modulus to 3.5 N/tex specific strength and 150 N/tex specific modulus. It also notes that Dyneema SK60 falls within this range at 2.7

N/tex and 90 N/tex. Thus, the DSM brochure refers to UHMW PE as polyethylene, and those skilled in the art do in fact refer to UHMW PE as polyethylene, just as the inventors did in the 446 Patent.

153. My opinion is further supported by the prosecution history of the 446 patent. Burgess discloses high molecular weight polythene (Ex. 7 at 1:13-14). During the prosecution history, Mr. Goodwin referred to the high molecular weight polythene disclosed in Burgess generically as “polythene,” which is the English term for polyethylene (Ex. 17 at DMI000595). Likewise, the Examiner twice referred to the high molecular weight polythene disclosed in Burgess generically as “polythene” (Ex. 17 at DMI000601). Notably, both the Examiner and the applicants referred to high molecular weight polythene by its generic or common, source-based name.

154. I disagree with Dr. Mukherjee that PE does not include UHMW PE to one of ordinary skill unless UHMW PE is specifically named. This statement makes no sense. It assumes that the well-accepted definition of PE is wrong and excludes UHMW PE. I know of no change in the well-accepted scientific naming conventions. While some authors may specifically refer to UHMW PE, my experience is that they do so when they want to emphasize the characteristics of UHMW PE as compared to PE. Here, the inventors of the 446 Patent had no reason to specifically refer to UHMW PE. PE was referred to as being lubricous. UHMW PE is lubricous. Therefore, there was no particular reason for the inventors to recite both PE and UHMW PE. Notably, the inventors referred to other materials such as nylon, aramid, PET, PTFE, PETFE, FEP, and PP generically as well. Therefore, the term PE was not treated any differently than the other materials. I note that Dr. Mukherjee does not read any other generic terms to

be limited to a certain range of the generic material. Further, Dr. Mukherjee equates the generic term "polypropylene" with a specific polypropylene, hard elastic polypropylene in the 688 patent. Thus, Dr. Mukherjee appears to read the generic term PE as limited, but not the other generic materials named in the 446 patent.

155. Dr. Mukherjee also states that the UHMW PE is not disclosed in the 446 Patent because PE is described in the 446 Patent as being "weak" which he states is inconsistent with UHMW PE (Mukherjee at 23). I disagree with both assertions. First, I disagree that the 446 Patent describes the first set of yarns being "weak." The 446 Patent never describes the first fiber-forming yarns as "weak." Instead, the 446 Patent, in one embodiment, describes the first set of yarns as lubricating yarns to "improve the overall pliability or compliance and surface lubricity of the heterogeneous braid" (Ex. 2 at 4:12-14). Dr. Mukherjee's statement that the first set of yarns are described as being too weak is just incorrect. Notably, in the background of the 446 patent it describes a "highly pliable braid" made from "highly lubricous polymers" in a "traditional manner" as being "relatively weak and unusable" in most cases (Ex. 2 at 2:22-25). But this is not a description of the highly lubricous *material* as "weak." Rather, it is a description of a certain *braid* – a *highly pliable braid* of just highly lubricous material -- as being weak, which is what one of ordinary skill would expect, because the material will likely slip (Ex. 8). I understand that Mr. Grafton constructed a braid of UHMW PE and had this very problem (Ex. 12. at 53-54).

156. Dr. Mukherjee's opinion appears to be based on a misunderstanding of the invention described in the 446 Patent He appears to equate lubricity with weakness and reads the 446 Patent, as describing braiding a weak yarn with a strong yarn. But

this is incorrect. The 446 Patent teaches, among other things, that a lubricious yarn can be braided with another yarn of different properties (*e.g.,* different lubricity, strength) to yield a braid that benefits from the lubricity of the first material and the strength of the second material. One of skill in the art, reading the 446 Patent, would understand that a braid of UHMW PE and PET would benefit from the lubricity of the UHMWPE and the strength of the PET. Dr. Mukherjee appears to assume that because in some embodiments the 446 Patent describes the first set of yarns as being for lubricity and the second set of yarns being for adding strength, that the first set of yarns must be weak. That is not stated in the 446 Patent. Nor would one of skill in the art read "weakness" into the 446 Patent.

157. I also disagree with Dr. Mukherjee's assertion that UHMW PE is not "weak." Although Dr. Mukherjee refers to yarns as being "weak," he does not describe in what sense they are weak. Thus, I am not sure what he means by weak. But, I note that Cohan described the tendency of monofilament UHMW PE to slip and the need for more complex knots when tying UHMW PE. In that sense, UHMW PE could be considered weak. I note that Arthrex made similar statements when applying for its own patent (Ex. 14 at 1:13-20). Arthrex reported in its 234 patent that UHMW PE "does not have acceptable knot tie down characteristics for use in surgical applications" (Ex. 14 at 1:20-21). Thus, with respect to knot hold, knot tie, and knot security UHMW PE may be considered "weak."

B. It Is My Opinion That 446 Patent Claims Are Not Invalid For Failing To Satisfy The Enablement Requirement

158. Dr. Mukherjee opines that when "viewed from the perspective of a person skilled in the art in February 1992, the 446 Patent does not teach a person how to make and

use a surgical suture including UHMWPE without having to resort to undue experimentation (Mukherjee at 25). I disagree. It is my opinion that the 446 Patent does teach a person of skill in the art in 1992 how to make and use the claimed surgical suture without having to resort to undue experimentation.

159. I note that Dr. Mukherjee only discusses whether a person of skill in the art could make the invention, and he does not describe whether they could "use" the invention. Therefore, I will only address the issue of making. For the reasons explained above, I disagree with Dr. Mukherjee regarding whether the 446 Patent disclosed UHMW PE to one of skill in the art. The 446 Patent describes how to make the claimed suture without undue experimentation. The 446 Patent states that the "heterogeneous braids of this invention can be prepared using conventional braiding technology and equipment commonly used in the textile industry, and in the medical industry for preparing multifilament sutures" (Ex. 2 at 4:60-62). The 446 Patent also describes a "plan view" of a yarn carrier layout for a carrier braiding machine for braiding (Ex. 2 at Fig. 1 and 4: 63-66). The 446 Patent then describes how to make a braid of two yarns by moving the braiding machine carriers (Ex. 2 at 4:67-5:26) and forming a braid that is in direct intertwining contact. The yarns claimed in the 446 Patent, including UHMW PE, can be braided on a conventional carrier braiding machine described in the 446 Patent. One of ordinary skill in the art in 1992 would have known after reading the 446 Patent how to braid UHMW PE with either nylon, aramid, or PET to form the claimed invention. My opinion is supported by Pearsalls, I note that Pearsalls makes FiberWire by braiding UHMW PE on a conventional braiding machine with PET.

160. The 446 Patent also provides specific guidance on manufacturing certain preferred embodiments. The 446 Patent notes that "yarn tension during braiding is advantageously adjusted so that the yarn elongation for each set of yarns is about equal" (Ex. 2 at 5:50-52). According to the 446 Patent, the "equilibration of yarn elongation may prevent irregularities, for example, core popping" (Ex. 2 at 5:53-54). Also, the 446 Patent advises that the "number of picks per inch in the finished braid can be adjusted to balance the tensile strength of the braid with braid quality, *e.g.*, the tendency of the core popping and overall braid smoothness" (Ex. 2 at 5:56-61). Adjusting braiding tension is a routine, common practice to one of skill in the art and something that is generally adjusted when constructing any braids. Thus, with this guidance provided by the 446 Patent one of skill in the art could have made a braid of UHMW PE with PET, aramid, or nylon.

161. Further, the 446 Patent describes two preferred embodiments. In the first, it discloses that a braid of 70 denier PET and 110 denier PTFE (Ex. 2 at 7:38-39). It also discloses that for that braid a 32 pick gear with a spring tension of 0.009" for the PET carriers and no spring tension with the PTFE carriers (Ex. 2 at 7:49-50). Also, it discloses a second embodiment of 75.5% PET and 24.5% PTFE with the same spring tension. Thus, the 446 Patent clearly advised one of skill in the art---what he already knew—to adjust the yarn tension when braiding to accommodate for the different yarn properties, including elongation characteristics.

162. The 446 Patent also describes several other conventional suture manufacturing processes that were well known to one of skill in the art in 1992, including,

scouring to remove machine oils and lubricants, stretching "*preferably*" at a temperature between the glass transition temperature and melting temperature of the lower melting set of yarns, annealing to improve dimensional stability, coating, and sterilization (Ex. 2 at 5:61-6:30). All of these general techniques were known to one of skill in the art in 1992. They were employed to make sutures. Based on the teachings set forth in the 446 patent, one of skill in the art could easily have adapted the known braiding techniques to braid UHMW PE with PET, nylon, or aramid to form the claimed invention without undue experimentation.

163. Dr. Mukherjee appears to provide two reasons why one of skill in the art in 1992 could not after reading the 446 Patent make a braid of UHMW PE with either nylon, PET, or aramid. He states that "UHMWPE is known to be extremely strong and to have low elongation" and that "[t]hese specialized properties must be taken into account when including UHMWPE in a braided structure as they will have an effect on the manufacturing process" (Mukherjee at 26). He also states that because "UHMWPE has such low elongation … [it]presents certain tensioning problems" (Mukherjee at 26). But Dr. Mukherjee does not describe what those "tensioning problems" are; why they are any different than braiding any two materials whose elongations do not match; and why it is beyond the routine skill in the art to adjust the braiding machine (*e.g.,* adjust the braid tensions of the different yarns) to compensate for the differences in elongation. In any event, the 446 Patent specifically disclosed braiding and adjusting the "yarn tension" to compensate for different material elongation. Thus, the 446 Patent specifically addresses the "elongation" issue that Dr. Mukherjee refers to and describes how to solve it. A person of skill in the art would know that when operating a braiding

machine, the tension of the yarns has to be adjusted to compensate for the elongation of the yarns. Braiding yarns with conventional braiders was well-known in 1992. There is nothing peculiar about braiding UHMW PE that would not have been known to the person of ordinary skill. It was within the routine work of a person of skill to adjust braiding tension.

164. My opinion is supported by the testimony of Mr. Hallet from Pearsalls. He testified that Pearsalls uses all known conventional equipment to braid UHMW PE. For example, Pearsalls has had the Hubourns braider that it uses to make FiberWire for about 55 years (Ex. 23 at 71:8-12). Further, Mr. Hallet described the braiding of FiberWire on conventional carrier braiding machines and adjusting the tension based on the yarns (Ex. 23 at 63:5-70:10). My opinion is further supported by the testimony of Arthrex's manufacturing witness, Mr. Dreyfuss, who said that, when Arthrex began developing FiberWire™, braiding the UHMW PE required only "normal development" and was done with "ordinary" braiding techniques.[5] Mr. Hallet testified that the tension had to be adjusted for various size FiberWire. That comports with my understanding of what was known to one of skill in the art in 1992 and why the 446 Patent would not need to specifically disclose braiding parameters specific to a certain size UHMW PE to be braided with another specific material on a specific machine.

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[5] [21:13 Q. When Arthrex began developing the FiberWire
21:14 suture, did it have any problems braiding the ultra high
21:15 molecular weight polyethylene?
21:16 A. I'm sorry; could you read that back?
21:17 (The requested portion of the record was read.)
21:18 A. Not that I'm aware of.
21:19 Q. It didn't -- The ultra high molecular weight
21:20 polyethylene didn't require any special braiding
21:21 techniques to produce a suture?
21:22 A. Nothing out of the ordinary.
21:23 Q. What does that mean?
21:24 A. Normal development. (Ex. 24)

165. To the extent that Dr. Mukherjee is stating that the 446 Patent should have disclosed more particular details, I disagree because such details are manufacturing details related to making a commercial product that I understand need not be disclosed. For example, providing a specific braiding tension is somewhat meaningless because it is so specific. It is dependent on the type of machine, the number of yarns, the material of the yarns being braided, the size of the yarns, the denier of the yarns and other factors. There are many variables in setting the braiding tension that persons skilled in the art are familiar with that there was no reason for the 446 Patent to specifically disclose a specific braiding tension.

166. Dr. Mukherjee also opines that the one of skill in the art could not after reading the 446 patent make the claimed invention with UHMW PE because “UHMW PE reacts differently to heat than any of the disclosed second fiber-forming materials” which affects the braid's reaction to hot stretching and the 446 Patent does not advise whether hot stretching is necessary when using UHMWPE. I do not fully understand Dr. Mukherjee’s opinion, so I am not able to respond. First of all, he does not define “hot stretching” so it is not clear what he means by the term. Further, it is not clear whether he believes that hot stretching a braid of UHMW PE is necessary, unnecessary, or necessary under certain parameters. Nor does he sufficiently identify what disclosure is allegedly missing from the 446 Patent so that, according to his opinion, one of skill in the art could not make the claimed suture in the 446 patent without undue experimentation.

167. Also, I note that Arthrex has a patent claiming sutures that claims a cover formed of a plurality of braided fibers which include UHMW PE (Ex. 14 at 3:13-17). I note that

Arthrex's patent provides no description of how to make a suture and certainly no description of what Dr. Mukherjee contends is absent from the 446 Patent. For example, Arthrex's 234 patent discloses two suture braids made on 16 and 12 carrier braiders with polyester and Dyneema, but does not disclose any braiding tensions, whether hot stretching is needed, or what temperatures at which to conduct any stretching, or how UHMW PE reacts to heat. If Arthrex's patent satisfies the enablement standard, I am not sure why the 446 Patent does not.

VIII. The Inventors Reduced the Claimed Invention to Practice

168. Generally, I understand that in order for a claimed invention to be actually reduced to practice, the invention must have been made and evaluated so that the inventors knew that it would work for its intended purpose.

169. I have reviewed Dr. Steckel's deposition transcript, Dr. Jamiolkowski's testimony, and Dr. Steckel's lab notebooks. It is my opinion that the inventors had made and tested a braided suture that was suitable for its intended purpose and had proved the concept of the invention at least as early as February 1989 and December 1989. I understand from Dr. Steckel's testimony that he referred to some of the work that led to the 446 patent as "Composite Braid Evaluation" or "CBE" (Ex. 25 at 135:1-21).

170. Dr. Steckel's notebook describes conception of the claimed invention at least as early as June 6, 1988 (Ex. 26 at DMI002617). Dr. Steckel describes his idea as "[a] preliminary evaluation of composite braids, *i.e.*, braided sutures constructed of two or more fiber types designed to realize the beneficial properties of each polymer" (Ex. 26 at DMI002617). He further states that the composite sutures to be evaluated included carrier blended "PET/PTFE" and "PET/PP" yarns in which blending occurs when two different yarns reside on different carriers during the braiding operation. (Ex. 26 at

DMI002617). Thus, at least as early as June 6, 1988, he had described the broad concept of a heterogeneous braided suture with two yarns in direct intertwining contact and provided two specific examples of braiding PET/PTFE and PET/PP (*see also* Ex. 27 at 99:7-25; 100:20-23; 102:10-17; 127:12-21; Ex. 25 at 159:6-23; 160:17-22; 161:4-10).

171. Dr. Steckel's notebook and testimony confirm that he built a suture braid as claimed in the 446 patent at least as early as June 6, 1988 (Ex. 26 at DMI002618; Ex. 27 at 127:12-128:21; Ex. 25 at 218:21-25). For example, Dr. Steckel built the CBE-15 prototype on June 6, 1988 with a carrier braider ("CB") (Ex. 26 at DMI002618). The CBE-15 braid was made from braid of 51% PET and 49% PTFE by volume (Ex. 26 at DMI002618). The yarns used to construct the CBE-15 braid are specified on page DMI002619 of Dr. Steckel's notebook (Ex. 26 at DMI002619). In June 1988, Dr. Steckel performed basic suture testing on CBE-15 including straight tensile and knot tensile testing (Ex. 25 at 219-220). Thus, at least as early as June 6, 1988, Dr. Steckel had conceived of the idea of braiding two materials, of the type claimed in the 446 patent, in direct intertwining contact to form a suture and had made a suture having these characteristics.

172. Dr. Steckel's notebook describes prototypes that he had constructed and tested as least as early as February 2, 1989 (Ex. 26 at DMI002635-38: Ex. 25 at 220-221). He had constructed PET/PTFE carrier braided sutures designated as CBE-15 having PET and PTFE yarns which were carrier braided in direct intertwining contact (Ex. 26 at DMI2635-36; Ex. 25 at 222-223). Dr. Steckel testified that "full characterization" of the braids had been completed at least as early as February 1989 (Ex. 25 at 218-219). His

notebook describes various testing that he performed on the braided sutures (Ex. 26 at DMI002637; Ex. 25 at 222).

173. Dr. Steckel had constructed and evaluated a suture that is within the scope of claims 1, 8, and 9 of the 446 patent at least as early as February 1989 (except it was not sterile). He had built a "heterogeneous suture" of PTFE and PET yarns. The PTFE and PET yarns were "continuous and discrete yarns" as claimed in the 446 patent (Ex. 2 at 8:65). They were also in "direct intertwining contact" because they were carrier braided (Ex. 2 at 8:67). The PTFE yarns were a "plurality of filaments of a first fiber-forming material," and the PET yarns were "a plurality of filaments of a second fiber-forming material" as claimed (Ex. 2 at 9:1-8). The volume fraction of the PTFE, the lubricating yarn, was 51% by volume (Ex. 26 at DMI002636). Further, Dr. Steckel had tested and evaluated the sutures. Therefore, he had reduced the sutures of claims 1, 8, and 9 to practice at least as early as February 1989.

174. I also note that Dr. Steckel built and tested prototypes in December 1989 (Ex. 26 at DMI2665-67). These prototypes were carrier blends of PTFE and PET yarns that were braided in direct intertwining contact (Ex. 26 at DMI2665). The specific braiding sequence is shown in Dr. Steckel's notebook (Ex. 26 at DMI2665). Similar to the prior PTFE/PET braids, these braids are also within the scope of claims 1, 8 and 9 of the 446 patent. Dr. Steckel evaluated the December 1989 prototypes and noted that the prototypes offered "exceptional handling properties for a braided suture" (Ex. 26 at DMI002665; Ex. 25 at 235:1-7). He also found that these prototypes "ranked better" in "handling properties" and knot-tie down relative to silk and Ethibond (Ex. 26 at DMI002666; Ex. 25 at 236:1-12). As he explained, the bending modulus of the

composite PTFE/PET suture braid was lower than silk and Ethibond (Ex. 26 at DMI002666-67). This means that the PTFE/PET braid was more flexible than silk and Ethibond. Dr. Steckel further noted that the intrinsic tensile and knot strength of the composite braid were 87 ksi. and 48 ksi. respectively. Based on Dr. Steckel's construction and evaluations, it is my opinion that Dr. Steckel had reduced to practice the claimed invention at least as early December 1989.

175. Dr. Mukherjee has opined that the inventors of the 446 patent did not actually reduce the invention to practice in February 1989 or prior to the February 19, 1992 filing date of the application. I disagree. The inventors had constructed a suture that they knew would work for its intended purpose.

176. Dr. Mukherjee opines that the inventors never actually reduced the claimed invention to practice because they did not construct a "sterile" suture (Mukherjee at 27-28). I first note that Dr. Mukherjee points to no specific testimony that says all of Dr. Steckel's braid constructions were not sterile. Dr. Mukherjee states that there was no reduction to practice because sterilization, generally, "*can* have a substantial effect on the braid properties" (Mukherjee at 28). But Dr. Mukherjee recognizes that this is only a possibility, not a fact. Also, Dr. Mukherjee provides no basis that this statement applies to any of the materials listed in the 446 patent. Further, he does not explain what effect he is referring to or under what conditions such effects may happen. Thus, even if the braids constructed by Dr. Steckel were not sterile, it is my opinion that the inventors had reduced the claimed invention to practice because the inventors had constructed and tested the claimed suture and knew that it would work as a suture for its intended purpose.

177. I also disagree with Dr. Mukherjee that sterilization was needed to reduce the claimed invention to practice because sterilization of medical devices including sutures were known processes that date well before the inventors work in 1988. The typical sterilization processes are gamma sterilization and ethylene oxide. Notably, the 446 Patent refers to both types of sterilization (Ex. 2 at 6:21-29). One of ordinary skill in the art would have been aware of both methods of sterilization and the parameters for sterilizing sutures and the materials claimed in the 446 patent. Further, one of ordinary skill in the art between 1988 and 1992 would have known that sterilization under normal conditions would not have had any substantial affect on braid properties, other than sterilization. Thus, there was no need for the 446 patent inventors to sterilize the sutures that they had constructed in order to show that they would work for their intended purpose and to prove the concept of their invention.

178. I further disagree with Dr. Mukherjee that sterilization was needed to reduce the claimed invention to practice because typically sterilization is done for product commercialization, not proof of concept. A suture designer would generally not sterilize his work unless it was to be tested in the body, or it involved product commercialization. Sterilization is basically a commercialization step that was not needed here to prove the concept of the invention claimed in the 446 patent. Requiring the inventor to sterilize the braided suture constructs would basically require him to make a commercial product and sterilize it in its packaging because typically sutures are sterilized in the packaging. In reality, suture designers do not sterilize suture designs to prove the concept unless the designs have something particular to do with sterilization. Here, the focus was on suture properties, and biological testing was not needed.

179. My opinion is supported by Mr. Grafton's deposition testimony concerning the development of the FiberWire product. Mr. Grafton testified that, after Arthrex tested the prototype suture braid of UHMW PE and PET, Arthrex believed it would work as a suture (Ex. 12 at 57). Although Mr. Grafton was not sure whether the sutures he tested were sterile or nonsterile (and I know of nothing indicating they were sterile), Mr. Grafton testified that sterilization would not be necessary at this stage of development, because it was only the mechanical features of the suture being tested, not the bio-burden levels (Ex. 12 at 60). Thus, Mr. Grafton's testimony supports my opinion that sterilization is typically not needed to prove the mechanical properties of a braided suture.

180. Dr. Mukherjee's testimony is contradicted by Arthrex's and Pearsall's own practices. I understand that Arthrex tested unsterile sutures when it tested coated and uncoated samples to show that FiberWire's coating has an effect on FiberWire's lubricity (Ex. 12 at 149). Arthrex's engineer who coordinated that testing was aware of the known sterilization techniques (Ex. 12 at 97). He must not have thought that sterilization could have a "substantial effect" on the braid properties, as suggested by Dr. Mukherjee, because otherwise he would have tested sterile sutures. If sterilization could have a "substantial effect" on the braid properties as Dr. Mukherjee suggests, then this casts doubt on the reliability of Arthrex's test results. Also, Pearsalls issued certificates of conformity on the braids that they made for Arthrex's FiberWire that describe certain suture properties such as knot strength. Arthrex has submitted these documents to the FDA. But Pearsalls does not sterilize sutures.

181. Dr. Mukherjee also opines that the 446 invention was not actually reduced to practice because there were "technical problems with the invention" (Mukherjee at 28-30). Dr. Mukherjee describes these problems as "core popping and braid looseness" (Mukherjee at 28). I disagree.

182. I first note that Dr. Mukherjee appears to take Dr. Steckel's "braid looseness" and "core popping" comments out of context. For example, Dr. Steckel testified that the CBE-15 suture braid has been made on June 6, 1988, and there is no core popping or braid looseness documented with respect to that construction. Rather, the only documented braid construction "issues" with respect to the June prototypes involved yarn blended prototypes, not the carrier blended prototypes, such as CBE-0015 (Ex. 26 at DMI02620). Further, there is no documented "core popping" or "braid looseness" with respect to the braids constructed and tested in December 1989. Thus, contrary to Dr. Mukherjee's suggestions Dr. Steckel had constructed PET/PTFE braids that did not have any "core popping" or "braid looseness" that was significant enough to document. Although Dr. Steckel did comment that the sutures evaluated in February 1989 had some "core popping" and "braid looseness," these were "infrequent" issues (Ex. 25 at 227-229). Most significantly, they did not prevent Dr. Steckel from constructing and evaluating the braids (Ex. 25 at 227-229). Anyway, only part of the braid that he constructed had core popping or braid looseness. Thus, the part that did not coupled with the other prototypes was more than sufficient to show that his sutures would work for their intended purpose. As Dr. Steckel stated, although certain prototypes had core popping and braid looseness, these issues did not prevent him from making and evaluating the suture and its properties (Ex. 25 at 228). For example, he did not have to

make 100 meters of perfect suture to prove that the suture would work for its intended purpose. It was more than sufficient to have some portion of the 100 meters that did not have core popping and braid looseness to show that he had built a suture that could work for its intended purpose (Ex. 25 at 229-230). For example, Dr. Steckel concluded that the December 1989 prototypes had "exceptional handling properties" (Ex. 26 at DMI002665). If core popping and braid looseness was as big a problem as Dr. Mukherjee suggests, then Dr. Steckel could not have made this conclusion.

183. I also disagree with Dr. Mukherjee's opinions that any "braid looseness" and "core popping" that the inventors experienced prevented them from making a product that would work for its intended purpose because these are really manufacturing/commercialization concerns, not proof of concept issues. "Core popping" and "braid looseness" are routine manufacturing details that are typically encountered when developing prototypes or even commercial products (Ex. 25 at 227). As Dr. Steckel testified, core popping and braid looseness are inherent in any braiding manufacturing process and quality control steps are used to eliminate any defective material when making commercial products (Ex. 25 at 227-231). "Core popping" and "braid looseness" are the type of details that are minimized when making a commercial product, so as to maximize the amount of manufactured suture that is suitable for a commercial product. My opinion is supported by the testimony of Brian Hallet of Pearsalls. As Mr. Hallet stated, core popping is a minor issue that generally arises in manufacturing braids (Ex. 23 at 192-193).

184. I also note that Dr. Mukherjee refers to a February 1990 memorandum discussing so-called "technical problems" (Mukherjee at 30). Based on all the testimony

and Dr. Steckel's notebook, I believe that he takes this memorandum out of context because it dealt with the issue of whether to pursue Dr. Steckel's concept further for certain purposes, not whether he had shown that the concept would work as a suture (Ex. 25 at 249-252). Also, I note that Dr. Mukherjee's processing "problems" discussion ignores the examples provided in the 446 patent (Ex. 2 at 7:36-63). These additional examples further show that the invention had been reduced to practice.

IX. Mr. Goodwin's Statement While Prosecuting the 446 Patent Was Not Inconsistent With Dr. Steckel's Testimony

185. I have read Mr. Witherspoon's report and, in particular, paragraphs 58-63 in which he suggests that Mr. Goodwin, one of the attorneys who prosecuted the 446 Patent, made an argument that was materially inconsistent with the testimony of Dr. Steckel. I have reviewed the arguments before the Examiner, the Burgess reference, and Dr. Steckel's testimony, and I do not agree for several reasons. First, Mr. Witherspoon misstates Mr. Goodwin's statement to the Examiner. Second, it is not clear what statements he is referring to from Dr. Steckel because he provides no citation. Third, Dr. Steckel's testimony is not inconsistent with Mr. Goodwin's statements, let alone materially inconsistent. Fourth, in any event, nothing was withheld from the Examiner because the application for the 446 patent discloses ultra high molecular weight polyethylene, UHMW PE.

186. I disagree with Mr. Witherspoon because he attributes a statement to Mr. Goodwin that he did not make. Mr. Witherspoon states that Mr. Goodwin represented to the Examiner that "if a medical designer were to actually build a suture using the braided combination of UHMW PE and polyester, then 'he would inevitably design an unacceptable suture'" (Witherspoon at ¶61). This is not what Mr. Goodwin said. Mr.

Goodwin said if a suture designer uses "*the teachings of the fishing line art* to modify a suture, then one would inevitably design an unacceptable suture" (Ex. 17 at DMI000608-609) (emphasis added). Thus, I disagree with Mr. Witherspoon because his opinion is factually incorrect; it is based on a statement that Mr. Goodwin did not make.

187. Even assuming that Mr. Witherspoon was referring to Mr. Goodwin's statement – if a medical designer uses "the *teachings* of the fishing line art to modify a suture, then one would inevitably design an unacceptable suture" -- I still disagree with Mr. Witherspoon. Mr. Goodwin's statement is a correct statement and there is nothing misleading about it. Burgess discusses a fishing line that is "non-stretchable" (Ex. 7 at 1). As Mr. Goodwin explained to the Examiner, those skilled in the art of developing surgical sutures would have known that it is important for a suture to have some stretchability for forming good knots. Further, as Mr. Goodwin also explained (Ex. 17 at DMI000607), Burgess does not mention knot security or knot strength or how the braid should be constructed to achieve them. Thus, if a suture designer followed Burgess' teachings about how to make a fishing line, one would be focusing on designing an acceptable fishing line, but not an acceptable suture.

188. I also disagree with Mr. Witherspoon because he does not specifically state what it is Dr. Steckel said that was inconsistent with Mr. Goodwin's statements (Witherspoon at ¶62). Mr. Witherspoon's report does not quote or cite to any specific testimony from Dr. Steckel. Rather, Mr. Witherspoon generally characterizes Dr. Steckel's testimony. Since he has not specifically identified Dr. Steckel's statement, it is difficult to address his opinions.

189. Nevertheless, even if Dr. Steckel said what Mr. Witherspoon believes he said, Dr. Steckel's testimony is not inconsistent with what Mr. Goodwin wrote to the Examiner. Mr. Goodwin's statement was directed to what a suture designer would do based on the teachings of Burgess, a fishing line reference. In contrast, Dr. Steckel's testimony was directed to his idea, not the teachings of a fishing line reference, and not how a suture designer would react based on Burgess. In fact, Dr. Steckel never testified about the substantive teachings of a fishing line reference nor the substantive teachings of Burgess, nor what would happen if a medical designer followed the teachings of a fishing line reference or Burgess. Thus, the statements are not inconsistent, let alone materially inconsistent.

190. I also disagree with Mr. Witherspoon's opinion because it appears to be based on the notion that Dr. Steckel and Mr. Goodwin did not inform the Patent Office that braiding UHMW PE and polyester would lead to an acceptable suture. But Dr. Steckel did describe his invention as including a braid of UHMW PE and PET (which is a polyester) in his patent application. Therefore, Dr. Steckel's testimony, that was allegedly not disclosed, was in-fact disclosed.

191. Not only were the statements consistent with Dr. Steckel's testimony, but they are true and, indeed, are supported by testimony of Arthrex's own witnesses. I understand that Arthrex witness, Don Grafton, testified at his deposition that knot tie down, which he defined as related to knot strength, would be poor with a UHMWPE suture (Ex. 12 at 26:14-31:1; 52-53). I also note that this is confirmed in the 234 patent application filed by Arthrex. Arthrex's 234 patent states that "[o]ne of the strongest materials currently formed into elongated strands is an ultrahigh molecular long chain

polyethylene, typically used for fishing line and the like, which is sold under the trade names Dyneema and Spectra. However, this material, while stronger than ordinary surgical suture, does not have acceptable knot tie down characteristics for use in surgical application" (Ex. 14 at 1:13-21). These statements appear to be consistent with Mr. Goodwin's statements to the Patent Office regarding the Burgess fishing line and contradict Dr. Witherspoon's opinion that there was something misleading about Mr. Goodwin's statements.

192. If necessary to further rebut any arguments made regarding Burgess, I may testify about the prosecution history of the 446 patent as it would be understood by a person of ordinary skill in the art. As explained above, the Examiner had rejected pending claims 21-24 as obvious over Burgess. The Examiner never stated what "braided construction" Burgess taught or that Burgess disclosed "direct intertwining contact." In responding to this office action, Mr. Goodwin argued that it would have been non-obvious based on differences between Burgess and the claims and fishing line and suture.

193. Mr. Goodwin explained that sutures must have good knot strength and knot security. This is accurate. He also explained that for fishing line knot security and knot strength are "not as critical" because they do not "keep a stitched wound intact" (Ex. 17 at DMI000607). Again, this is accurate and supported by the fact that Burgess does not discuss either knot strength or knot security.

194. The main focus of Mr. Goodwin's response was that since Burgess describes fishing line design criteria that are different from suture design criteria, one of ordinary skill in the art would not look to Burgess. But even if a medical designer did consider

Burgess, Burgess does not disclose any particular braid, and he would be led down a path of designing a suture to achieve the fishing line properties disclosed in Burgess, not a suture that maximizes suture properties. Burgess says nothing about how to make a braid to achieve knot security or knot strength.

195. At trial, I may use demonstrative exhibits that I have not yet created to further explain my opinions.

Dated: March 24, 2006

Matthew Hermes Ph.D.

CERTIFICATE OF SERVICE

I certify that the foregoing Expert Report of Dr. Matthew Hermes was served by e-mail without exhibits and Federal Express overnight mail (Saturday delivery) with exhibits on March 24, 2006 on the following:

Charles W. Saber
Dickstein, Shapiro, Morin & Oshinsky, LLP
2101 L. Street, NW
Washington, DC 20037-1526.

Christopher Weld, Jr.
Todd & Weld LLP
28 State Street, 31st Floor
Boston, MA 02109

Dated: March 24, 2006

Erich M. Falke

EXHIBIT 9

SALES BULLETIN

DATE **01/05/05** SUBJECT **High Strength Sutures** NUMBER **UE133**

A Biomechanical Analysis of High Strength Sutures

Recently, Stephen S. Burkhart, M.D., conducted a biomechanical analysis of new high strength sutures used primarily for arthroscopic shoulder surgery. The purpose of the study was to determine the type of braided suture that produces the optimal knot configuration maximizing both knot and loop security. The high strength sutures tested were #2 FiberWire®, #2 OrthoCord™, Herculine™, MaxBraid, UltraBraid™, and Ethibond™ (2 mm FiberTape™ was also included in this study).

Conclusions

- Tying a surgeon's knot with #2 FiberWire significantly increases knot security compared to #2 OrthoCord, #2 Herculine, #2 MaxBraid, #2 UltraBraid, and #2 Ethibond.
- Tying a surgeon's knot or sliding knot with #2 FiberWire provides the optimum balance of loop and knot security compared to #2 OrthoCord, #2 Herculine, #2 MaxBraid, #2 UltraBraid, and #2 Ethibond.
- #2 FiberWire provides the greatest loop security when tying a Weston or Roeder knot compared to #2 OrthoCord, #2 Herculine, #2 MaxBraid, #2 UltraBraid, and #2 Ethibond.
- #2 FiberWire has the greatest knot security when tying a surgeon's knot compared to #2 Herculine, #2 MaxBraid, #2 UltraBraid, and #2 Ethibond. Although #2 OrthoCord had the smallest loop circumference when tying a surgeon's knot the difference between the loop circumference of #2 FiberWire and #2 OrthoCord **was not** statistically significant.
- In straight pull-testing, #2 FiberWire had the highest ultimate strength compared to #2 OrthoCord, #2 Herculine, #2 MaxBraid, #2 UltraBraid, and #2 Ethibond.
- #2 FiberWire had the smallest percentage of elongation compared to #2 OrthoCord, #2 Herculine, #2 MaxBraid, #2 UltraBraid, and #2 Ethibond.

Methods & Materials

Six #2 sutures were tested, FiberWire (polyethylene & polyester), Ethibond (polyester), OrthoCord (polydioxnone & polyester), Herculine (polyethylene), MaxBraid (polyethylene), and UltraBraid (polyethylene with & without a monofilament polypropylene marker). Three knots were used, the Roeder & Weston knots with three reversing half-hitches on alternating posts as well as a static surgeon's knot. Additionally, 2 mm FiberTape (polyethylene & polyester) were tied using four alternating throws. All total 133 knots were tied.

All knots were tied around a 30 mm circumference post to assure consistent loop circumference by Stephen S. Burkhart, M.D., a senior arthroscopic surgeon (Figure 1). Before testing, the knot stack was measured using calipers (Figure 2).

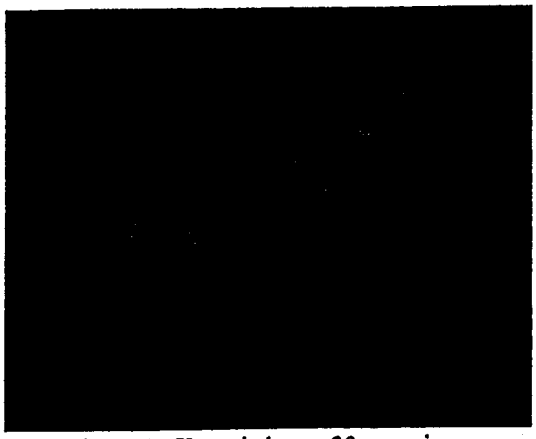


Figure 1: Knot tied over 30 mm pin.

Figure 2: Measuring knot stack.

Each loop was mounted on an Instron materials testing system (model 5544, Instron, Canton, MA) to test knot and loop security. Fixtures were mounted to the base and crosshead of the Instron with two 3.95 mm diameter rods held parallel. Each loop was placed around the rods with the knots centered between the two rods (Figure 3). A 5N preload was applied at 1 mm/s and then pulled to failure at 1 mm/s. Data was collected at 500 Hz.

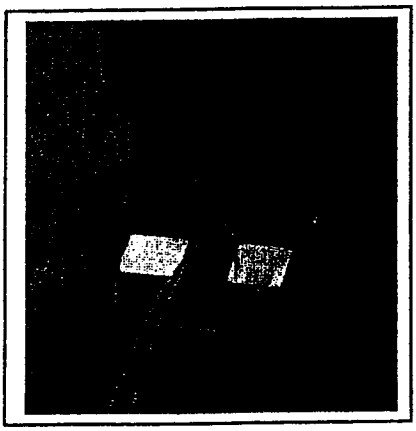


Figure 3: Instron test set up.

The loop circumference was measured at the 5N preload to assess each knot's ability to maintain a tight loop without slippage (loop security). The loop circumference was calculated based on equation 1 where C_l = loop circumference, d = rod diameter, and x = crosshead displacement measured for the center of each rod.

Equation 1: $C_l = \pi d \times 2(x)$

Knot security was measured as the maximum force to failure at 3 mm of crosshead displacement or suture breakage during single pull load testing (force to failure and failure mode were recorded). Three millimeters of elongation was selected as the failure mode because 3 mm or more is generally accepted in the literature. For statistical analysis one way analyses of variance (ANOVA) were used. *Post hoc* pairwise multiple comparisons were made using a Biferroni t-test. A significance level of 0.05 was used for all analyses.

EXHIBIT 10

Arthrex, Inc., Naples, FL
Test Report Summary and Sign-Off Sheet

Ref: RAF-04.16-1
Rev: 3
Date: 01/08/04
Approved DCN: 03310

Test Report: # TEST021104

Part number:	Rev:	Description:	Material:
DT PS05 T2	N/A	#2 Fiberwire MED2174 Coated and Uncoated USIPG Dyed	Polyethylene, Polyester
Vendor Name: Pearsalls Brian Hallet.		**Lot Numbers:** N/A	**Number Tested:** 3/2
Performed by: Ashley Holloway		**Type of Test:** Knot Tiedown	**Date:** 02/16/04

Test Objective:

To determine the peak force required to advance a single half hitch using coated and uncoated Fiberwire suture.

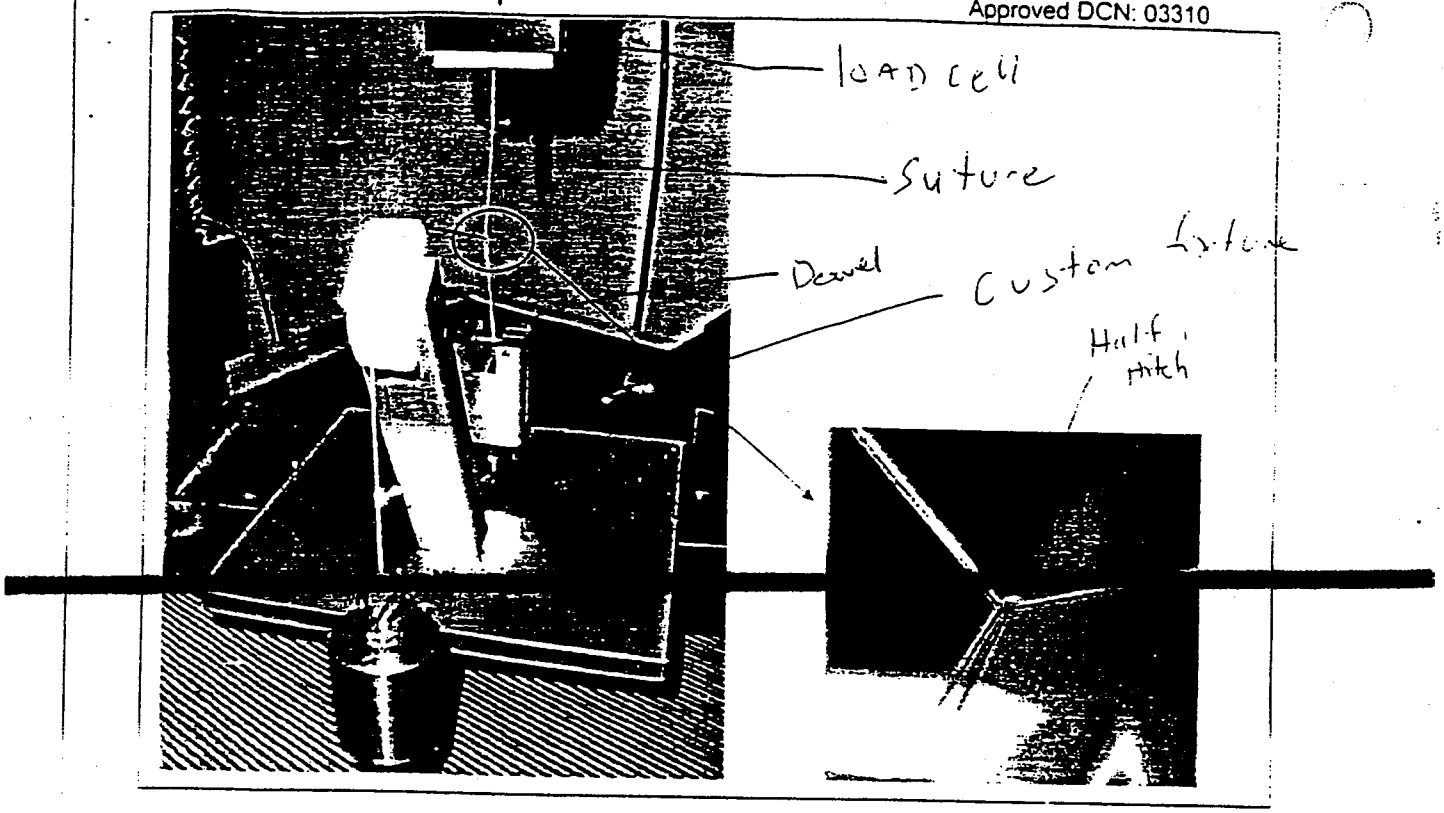
Materials and Methods:

The 50lb load cell was attached to the MTS Sintech 1/S and calibrated. A custom fixture as shown was used to simulate knot tying that would occur clinically. The top end of the suture was clamped in a custom fixture that was attached to the load cell, and then a single half hitch was tied around a guide block such that the loop length was consistent between samples. A weight of .375 kg was then attached to the free end of the suture in order to tension the loop. Care was taken to tension the legs of the suture consistently. The loop was then loaded at 12 in/min for 30mm and data was collected at 200 Hz. The peak load required to cause the half hitch to slip was recorded and used for data analysis purposes.

DEPUY MITEK
EXHIBIT 343
04cv12457

Arthrex, Inc., Naples, FL
Test Report Summary and Sign-Off Sheet

Ref: RAF-04.16-1
Rev: 3
Date: 01/08/04
Approved DCN: 03310



Data Analysis/Conclusions:

A mean peak force of 12.7 N was recorded for the coated suture. This force represents the force required to initiate slippage of the half hitch. A mean peak force of 32.9 N was recorded for the uncoated suture. A significantly greater amount of force was required to advance the uncoated suture.

2/16/04

Sample ID: coated_uncoated suture_1_021004.mss
Method: Suture Test.msm

Test Date: 2/11/04
Operator: Ashley Holloway

Sample Information:

Name	Value
Lot Number	n/a
Part Number	Coated/Uncoated suture test
Revision Level	#2 Fiberwire

Specimen Results:

Specimen #	Peak Load Coated (N)		Specimen #	Peak Load Noncoated (N)
1	12.43		4	34.04
2	13.08		5	31.71
3	12.64			
Mean	12.72			32.88
Std. Dev.	0.33			1.65
Minimum	12.43			31.71
Maximum	13.08			34.04

Calculation Inputs:

Test Inputs:

Name	Value	Units
Break Threshold	5.620	lbf
Brk Sensitivity	95	%
Data Acq. Rate	200.0	Hz
Ext Limit HI	30.0	mm
Initial Speed	300.00	mm/min
Load Limit HI	150	N
MaxSpecimens	999	
Outer Loop Rate	100	Hz
Slack Pre-Load	5.00	N
Slowdown Extension	0.000	in
Slowdown Load	0.000	lbf
Slowdown Strain	0.000	%
Test Speed	305.00	mm/min

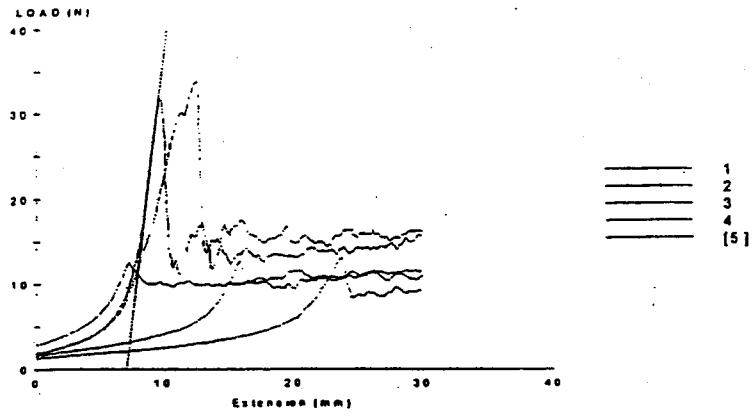


EXHIBIT 11

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

DePuy Mitek, Inc., a Massachusetts Corporation,

Plaintiff,

vs.

CIVIL ACTION
NO. 04-12457 PBS

Arthrex, Inc., a Delaware Corporation,

Defendant.
_____/

DEPOSITION OF: DONALD GRAFTON

DATE: March 14, 2006

TIME: 8:38 a.m. to 1:23 p.m.

LOCATION: The Ritz Carlton Golf Resort
2600 Tiburon Drive
Naples, FL 34112

TAKEN BY: Plaintiff

REPORTER: Deborah A. Krotz, RPR, CRR

VIDEOGRAPHER: Gene Howell, CLVS

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A. What's the date on this?
Q. The date on this is -- the last page is dated November 4th, 2005.
A. Okay. I want to quantify this then, because you're talking about a time period after I worked for the company, so when you -- when it says in here that I'm familiar with these products, it would be at the time I had left the company. And this is -- this was written after I left the company. So I can't totally say that I am familiar with those products under that.
Q. So you would agree that you were familiar with the state-of-the-art for surgical suture products as of the date you left Arthrex?
A. Define state-of-the-art, sir.
Q. State-of-the-art? Well, the general -- You don't have an understanding of what that means?
A. I want to understand what you mean in the context of this state-of-the-art.
Q. Okay.
A. I mean there's -- there's -- there's --
Q. This is from Pearsalls, so I can't tell you exactly what they mean, so ... Let me back up. When you were --
A. I was -- I was familiar with the competitive products on the market and what we offered and how they

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compared to the competitive products.
Q. Okay. And that was as of the date you left Arthrex?
A. Yes.
Q. Okay. And how long were you familiar with Arthrex's suture products and the competitive suture products that are in the marketplace?
A. When we started marketing the product, the sutures, until the time I left.
Q. Okay. So sometime when Arthrex began selling the suture from the supplier from New Mexico?
A. Yes.
Q. Okay. When Arthrex shifted from the Pearsalls suture to the Tevdek suture, was there any consideration to -- or for Arthrex designing its own suture?
A. No.
Q. Why not?
A. Because we could find a suture OEM that was available already. Why manufacture the suture when there's a readily available source?
Q. Now you said you tested for the Tevdek suture before it was selected; right?
A. Of course.
Q. And then it came back after it was selected, the response from surgeons was that it had low knot strength

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and tensile strength; right?
A. Yes.
Q. Didn't that come up in your testing?
A. I don't recall.
Q. What was your involvement in the development of FiberWire?
A. It was my idea.
Q. When you say it was your idea, what do you mean by that?
A. I'll give you -- Would you like the story on how FiberWire came about?
Q. Sure.
A. We were having issues from customers with the Tevdek suture being low tensile strength as compared to competitors' suture anchors with suture, primarily Ethicon.
Q. Ethibond?
A. Ethibond. This was numerous complaints from friendly surgeons, not -- not a massive amount of complaints, but it was determined that the tensile strength of the suture was not as good as the Ethicon Ethibond suture.
Q. When you say friendly, do you mean friendly to Arthrex?
A. Yes. And I had gotten a phone call from a Dr.

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Deberdino who was a surgeon at Fort Sam Houston, San Antonio. His -- his comments were that he had tied three knots the previous afternoon using the FASTak product of Arthrex -- that's a glenoid labrum device -- and had broke the knots on all three of them. And -- you know -- he said it kind of jokingly. He said, "And I didn't even work out the day before."
And so he was tying to be nice about it, but bottom line was your suture sucks. Okay?
And so -- you know -- we're in a position where we need to find a suture that will be competitive. I had been to Pearsalls many times working on bioabsorbable products. This was the time that you referred to earlier where I said three to five, and was familiar with suture manufacturing, the steps required to manufacture a suture.
One of the trips there, Mr. Lyon had pointed out to me a -- the other products they manufactured, which was fishing line and silk used in decorated drapes. The fishing line used a ultra-high molecular weight polyethylene material that was very strong, and I -- at some point, it was decided that we would try some of that for a suture.
I had Pearsalls, mainly through Brian, as being the manufacturing person --
Q. Brian Hallett?

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A. That's correct -- make some Size 2 braided material, send to me, and at the -- coincidentally, at the same time, I had a Dr. Steve Burkhart from San Antonio and a Dr. Casey Chan, who is a R & D guy in knot testing and suture. They were -- they were at Arthrex at the time when this material showed up.

We tested the material. The strength was excellent. The knot slippage was very poor, would not hold a knot.

So at that point in time, it looked like we would not be able to use an alternative material of ultra-high molecular weight polyethylene because the slippage of the material -- because of the slippage of the material tested with Casey Chan -- Dr. Chan and Dr. Burkhart. And so at that point in time, the -- the product was -- was on hold.

I was on a trip to Chicago to the national sales meeting, and I had this idea of adding PET to the ultra-high molecular weight polyethylene to enhance the or reduce the knot slippage of the product. I sent an e-mail to Dr. Steve Burkhart and suggesting that since he was familiar with the testing we had done very recently with just the ultra-high molecular weight PE, of adding the PET, and his -- I'll never forget the e-mail. He thought that was a killer idea.

And so I had asked then at that time for Brian

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Hallett to make me samples up of using those two materials and -- and send to me. And we tested the materials, and now we had a product that had superior tensile strength and greater knot strength than any competitive product out on the market.

Q. Okay. If I could just back up to a couple of points that you mentioned to make sure I understand what happened here. The -- You said the idea began -- or I'm sorry. Back up. You said when this idea came up, you had already been to Pearsalls several times?

A. Mmm-hmm (affirmative).

Q. And you were familiar with --

A. Yes.

Q. And when this idea came up, you were familiar with how sutures were manufactured?

A. Yes.

Q. Okay. And what did you mean by that?

A. One of the products -- projects that I worked on was a bioabsorbable suture similar to what Ethicon sells as Panacryl, and the difference being this was 100 percent PLLA material. The -- so we worked on this for about a year -- I don't know the exact time -- with many trips over to Pearsalls to change the construct of the yarn to enhance the tensile properties of the material. And so at that time, I became familiar with how a suture is

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processed to make a braid.

Q. Okay. And how many times were you over in England?

A. I told you already. Three to five.

Q. Three to five.

A. Approximate.

Q. Is that total lifetime?

A. That's an approximate number total lifetime, yes.

Q. Have you been to other manufacturing facilities for sutures?

A. Jenzyme Tevdek.

Q. And how many times have you been there?

A. Once, I believe.

Q. And when you were at Jenzyme Tevdek, did you see the manufacturing processes for Tevdek?

A. It was a dog and pony quick courtesy through the facility.

Q. So when you came up with the idea for using ultra-high molecular weight polyethylene in a suture, did you -- you say you are familiar with how sutures are made?

A. I'm also a fisherman. There's -- you know -- fishing line is -- uses ultra-high molecular weight polyethylene as a material that's used for sport fishing, very high strength.

Pearsalls made fishing line. And so they had

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this material already available as a fishing line. So it was an easy conversion -- you know -- conclusion, conversion to say what if this is used as a suture material, because ultra-high molecular weight polyethylene is a totally inert material.

Q. When you saw that Pearsalls had been using ultra-high molecular weight polyethylene in fishing line --

A. Yes.

Q. -- do you know how it was being used in fishing line, what the construction was?

A. No.

Q. Was it a braided construction? Was it --

A. I can't tell you for sure, sir.

Q. You don't know?

A. I wasn't interested in buying fishing line, so I didn't look at the details of it.

Q. So you had -- Sitting here today, you can't tell me anything at all about how the fishing line that Pearsalls was making with ultra-high molecular weight polyethylene was constructed?

A. It went through their manufacturing processes in their company, but specifically how it was made, the constructs, I have no idea or the size.

Q. In other words, you have no idea if it was all

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ultra-high molecular weight polyethylene or if it was braided or --
A. It's been too long ago. I can't tell you that.
Q. And your idea was to use the ultra-high molecular weight polyethylene as a suture?
A. Yes.
Q. Okay. And you had Mr. Hallett make a Size 2, I think you said?
A. Yes.
Q. Okay. Can you describe the construction of that first --
A. I don't remember now. It's been too long.
Q. Was it all ultra -- ultra-high molecular weight polyethylene?
A. Initially, yes, as a test prototype material.
Q. Was it braided?
A. Yes.
Q. Was it an eight-carrier or a sixteen-carrier?
A. I don't remember.
Q. You said it was a Size 2 though?
A. Yes.
Q. So it was a Size 2 ultra-high molecular weight polyethylene braided suture that did not have PET?
A. For the initial prototype material, that's correct.

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Q. Okay. And it didn't have nylon or any other material braided with it?
A. No.
Q. So the initial prototype was a ultra-high molecular weight polyethylene braided suture prototype, if you will?
A. Yes. Size 2.
Q. Size 2. And was the initial prototype, was it coated?
A. I don't remember.
Q. Okay. Do you know if the initial prototype went through any other manufacturing process like stretching or heating, twisting?
A. I don't recall.
Q. Was the initial prototype 100 percent ultra-high molecular weight polyethylene?
A. For the fourth time, yes.
Q. Okay. And you tested the initial prototype that was 100 percent ultra-high molecular weight polyethylene with Dr. Burkhart and Dr. Chen?
A. Dr. Casey Chen, correct.
Q. Okay. And the test that you conducted with Dr. Burkhart and Dr. Chen on the ultra-high molecular weight polyethylene was a knot strength test?
A. Knot security.

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Q. Knot security test?
A. Yes.
Q. Was that the test we drew in Exhibit Number 421?
A. That's correct.
Q. Okay. And you said the strength was excellent, I believe, of the initial prototype, but the knot slippage was poor; is that right?
A. Yes.
Q. Okay. When you say the slippage was poor of the initial prototype, what do you mean?
A. Less than the tensile strength capability of the existing Arthrex product.
Q. So the knot slippage was less than the Tevdek suture?
A. Yes.
Q. And it was -- knot slippage was such that it was determined that the 100 percent ultra-high molecular weight polyethylene suture prototype wasn't suitable to be developed?
A. That's correct. Yes.
Q. Okay. Ultra-high molecular weight polyethylene, you said the knot slippage was poor?
A. (Witness nods head affirmatively).
Q. Ultra-high molecular weight polyethylene, is that a lubricious material?

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A. Yes.
Q. And was the knot slippage of this ultra-high molecular weight polyethylene poor security because of the lubricity of polyethylene?
A. Yes.
Q. Yes?
A. Yes.
Q. So then you came up with the idea to braid PET with the ultra-high molecular weight polyethylene to reduce the knot slippage?
A. Yes.
Q. And when you say knot slippage, we're referring to this knot security test?
A. Yes.
Q. So are we using the terms knot slippage and knot security interchangeably here?
A. You are, yes.
Q. In your testimony?
A. Yes.
Q. So the knot security of the 100 percent ultra-high molecular weight polyethylene was poor, the prototype; right?
A. Yes.
Q. And your idea was to add the PET and to improve the knot security?

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MR. SOFFEN: Objection; asked and answered. You've asked him the same thing multiple times. But you can answer.
A. I've lost count, it's been so many times, but the answer again is yes.
Q. Okay. And Dr. Burkhart said that was a killer idea?
A. What was a killer idea?
Q. The killer idea was that your idea of adding PED -- PET -- I'm sorry. I'll rephrase that question.
Did Dr. Burkhart say that your idea to braid PET with the ultra-high molecular weight polyethylene to improve knot security was a killer idea?
A. Yes.
Q. Okay. And then you said you had Pearsalls manufacture a prototype that had PET and ultra-high molecular weight polyethylene braided?
A. Yes.
Q. And you tested that prototype?
A. Yes.
Q. And you said that that prototype had good knot strength?
A. Correct.
Q. And the prototype of PET braided with ultra-high molecular weight polyethylene had good knot security?

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A. Yes.
Q. And the prototype of PET and ultra-high molecular weight polyethylene braided together also had good tensile strength?
A. Yes.
Q. And after you tested this second prototype, if you will, of the PET braided with ultra-high molecular weight polyethylene, was then the decision made to pursue trying to commercially develop this idea?
A. Yes.
Q. Did you -- when you made -- Who made the decision to go forward and try to commercialize this idea?
A. Myself and Reinhold, surgeons that we collaborated with, marketing people. You know, it wasn't just myself.
Q. Okay. Was this prototype that had the PET braided with the ultra-high molecular weight polyethylene, was it -- did it have a coating on it?
A. Yes.
Q. It did?
A. (Witness nods head affirmatively).
Q. And what was the coating?
A. I forget the name. It's like an MED2174s.
Q. That was on the prototype?
A. Which prototype are you referring to now?

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Q. I'm talking about the --
A. The second prototype with the PET?
Q. Correct.
A. Yes.
Q. The second prototype that had the coating on it?
A. Yes.
Q. And was that part of your initial idea, or was that -- because I thought you said your initial idea was to add the PET. Was it also to coat it, or was that something that came later?
A. If you're going to market the product, it needs the coating on it, sir.
Q. Okay. But the prototype that was manufactured that you asked --
A. Most likely, it was coated, because it needed to be as the final product would be marketed.
Q. You said most likely. Do you remember or you don't remember whether the prototype that had the PET and the ultra-high molecular weight polyethylene was coated?
A. I can't tell you for sure that it was at that prototype stage.
Q. Okay. Was this prototype that you had -- after you tested the prototype with PET with ultra-high --
A. Excuse me. I want to change that.
Q. Okay.

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A. I never got samples of constructions from Pearsalls without a coating unless I specifically asked for it not to be coated. So there's a very high probability that the suture came as -- the second prototype -- as coated.
Q. That was standard for them to coat it, in other words?
A. Yes.
Q. Okay. So the initial prototype that was ultra-high molecular weight polyethylene, did you ask for that not to be coated?
A. No.
Q. So chances are that that one was coated?
A. Quite possibly.
Q. After you tested the prototype of PET and ultra-high molecular weight polyethylene braided together, did you believe that it would then work as a suture?
A. Yes.
Q. Okay. Is there anything else you think you needed to do in order to determine whether it would work as a suture?
A. Yes.
Q. What did you need to do?
A. Biocompatibility toxicity testing, bioburden levels, all the design control GNP items that need to be

EXHIBIT 12

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

DePuy Mitek, Inc., a Massachusetts Corporation,

Plaintiff,

vs. CIVIL ACTION NO. 04-12457 PBS

Arthrex, Inc., a Delaware Corporation,

Defendant.
_____/

CONTINUATION
DEPOSITION OF: PETER DREYFUSS

DATE: December 7, 2005

TIME: 8:03 a.m. to 1:21 p.m.

LOCATION: The Staybridge Suites
4805 Tamiami Trail North
Naples, FL

TAKEN BY: Plaintiff

REPORTER: Deborah A. Krotz, RPR, CRR

VIDEOGRAPHER: Michael Sturdevant, CLVS

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Q. And if you see in the second paragraph, second sentence, it says, "The Black/White Suture commonly known as TigerWire has a blend of nylon and the ultra high molecular weight polyethylene." Do you see that?
A. Yes.
Q. And if you skip a sentence, it says, "In place of the nylon, a silk suture will be used." Do you see that?
A. Yes, I do.
Q. Is the only difference between Arthrex's TigerWire and Arthrex's FiberWire with silk is the silk suture is used in place of the nylon marker strand in Arthrex's TigerWire product; is that right?
MR. SABER: Object; vague and confusing question.
Q. Do you understand the question?
A. I understand, I believe, from what I read here that that is true.
Q. And the last time we were here, you described the design and construction of the TigerWire product. Do you remember that?
A. Yes, I understand that.
Q. What is the purpose of the nylon marking strand in Arthrex's TigerWire product?
A. Identification. Visual identification.
Q. Is there any other purpose to the nylon marking strand in Arthrex's TigerWire product?

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A. That's the primary purpose. I'm not sure if there's secondary purposes, per se.
Q. Does the introduction of a nylon marking strand in the TigerWire product affect any of the physical characteristics of the TigerWire product?
A. Affect in --
Q. Other than the visual distinction that you can see with the introduction of a nylon marking strand, does the nylon marking strand in TigerWire affect any other characteristic of the braided suture?
A. Yes.
Q. What is -- what?
A. Minute differences in its feel and strength, characteristics.
Q. But you would describe them as minute differences?
A. Not enough to cause it not to become a product.
Q. Can you explain that?
A. It's --
Q. In other words, the introduction of the nylon marking strand doesn't affect any of the marketing qualities or engineering qualities that make FiberWire FiberWire; does that make sense?
MR. SABER: Objection; vague.
A. It -- They are comparable.

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Q. But they show -- But a No. 2 TigerWire, for instance, and a No. 2 FiberWire show very similar knot strength, tensile strength, handleability, and what not, all of the characteristics that define FiberWire?
A. I believe so.
Q. Okay. And is that true also with the introduction of silk rather than a nylon marker?
A. I don't know.
Q. Do you know whether the silk used in the FiberWire with silk suture affects any of the characteristics of the suture?
A. No, I don't.
Q. Based on your understanding of Arthrex's FiberWire with silk product, do you think you would be able to draw a cross-section of the suture?
A. I -- No.
Q. No? But as far as you know, the only difference between the TigerWire and a FiberWire with silk is instead of the nylon, it's a piece of silk?
A. That would be a good generalization.
Q. Okay. And Don Grafton would know this information?
A. I believe so, yes.
(DePuy Mitek Exhibit No. 142, Design History File for FiberWire 3-0 and 4-0, ARM 6580 through 6950, was

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marked for identification.)
Q. I'm going to hand you a document labeled DePuy Mitek Exhibit 142. It's a document with Bates numbers ARM 6580 through 6950.
Have you seen Exhibit 142 before?
A. I believe so.
Q. And what is DePuy Mitek Exhibit 142?
A. The Design History File for FiberWire new sizes -- new sizes of FiberWire.
Q. And what new sizes for FiberWire?
A. 3-0 and 4-0.
Q. Do you have any reason to believe the information in Exhibit 142 is inaccurate?
MR. SABER: Objection; overbroad.
A. No, I don't.
MR. FALKE: I'm just trying to authenticate the document.
MR. SABER: No, I have no problem with you authenticating the document, but I -- you know -- this is, again, a document of hundreds of pages. And to ask him to -- a generalized question like that I think is kind of unfair.
BY MR. FALKE:
Q. Do the instructions for use that are included with all of Arthrex's FiberWire product indicate that the

EXHIBIT 13

First Sale of Part #'s with Fiberwire

Part #	Invoice #	Sales Order		Date
AR-7209SN	IV775366	S750821		5/24/2004
AR-7219	IV718668	S696876		2/19/2004
AR-1920BFT	IV720917	S698914		2/24/2004
AR-1920BF	IV507362	S490302		12/23/2002
AR-1925BF	IV525206	S508102		2/3/2003
AR-1920BNF	IV651950	S631500		10/23/2003
AR-1925BNF	IV665050	S644075		11/17/2003
AR-1902SF	IV567520	S549306		4/29/2003
AR-1915SF	IV499913	S482926		12/6/2002
AR-1920SF	IV630756	S610779		9/4/2003
AR-1925SF	IV617604	S597769		8/13/2003
AR-1928SF	IV578475	B560330		5/22/2003
AR-1928SNF	IV793431	B769413		6/28/2004
AR-1324BF	IV456286	S438187		8/21/2002
AR-1324BF-2	IV518381	S501012		1/20/2003
AR-1934BF	IV455709	S437535		8/20/2002
AR-1934BF-2	IV518470	S501400		1/20/2003
AR-7200	IV313535	S296191		8/9/2001
AR-7202	IV449860	S431942		8/2/2002
AR-7204	IV556046	B538607		4/4/2002
AR-7205	IV720151	S698352		2/23/2004
AR-7207	IV758811	S734791		4/26/2004
AR-7210	IV383632	S365480		2/20/2002
AR-7211	IV485324	S467769		11/1/2002
AR-7220	IV517123	S500083		1/16/2003
AR-7221	IV518488	S501431		1/20/2003
AR-7225	IV570854	S552835		5/6/2003
AR-2225S	**IV616483**	**S596712**		**8/11/2003**
AR-7227-01	IV781308	S756864		6/3/2004
AR-7227-02	IV780119	S755625		6/2/2004
AR-2226S	**IV791766**	**S767483**		**6/23/2004**
AR-7228	IV566034	S548130		4/25/2003
AR-7230-01	IV772818	S748209		5/19/2004
AR-7230-02	IV792330	S767941		6/24/2004
AR-1322BNF	IV521513	B504899		1/27/2003
AR-1322-752SF	IV518341	S518341		1/20/2003
AR-1324HF	IV662450	S662450		11/11/2003
AR-1324SF	IV459020	S440859		8/28/2002
AR-1322SXF	IV464295	S446283		9/11/2002
AR-7201	IV489157	S471372		11/12/2002
AR-7203	IV555999	S538522		4/3/2003
AR-7205T	IV710484	S689254		2/6/2004
AR-7209	IV484118	S466521		10/30/2002
AR-7209T	IV612329	S592805		7/31/2003
AR-7222	IV724540	B702613		3/1/2004
AR-7237	IV762680	S738906		4/30/2004
AR-7229-12	IV750929	S727156		4/13/2004
AR-7229-20	IV761187	B737692		4/29/2004
AR-1925BNP	**IV831261**	**S807832**		**9/9/2004**
AR-1920SNF	**IV898169**	**S875373**		**12/30/2004**
AR-1920BNP	**IV831261**	**S807832**		**9/9/2004**
AR-1927BF	**IV918263**	**S897528**		**2/1/2005**
AR-1920BT	**IV848270**	**S825641**		**10/8/2004**
AR-7219	**IV707696**	**S686712**		**2/2/2004**
AR-11796	**IV731910**	**S709391**		**3/11/2004**
AR-1929	**IV440376**	**S422269**		**7/9/2002**

"Confidential-
Outside Attorneys'
Eyes Only"

EXHIBIT 14

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS
C.A. No. 04-12457 PBS

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DePUY MITEK, INC.,
A Massachusetts Corporation,
Plaintiff,
v.
ARTHREX INC.,
A Delaware Corporation,
Defendants.

----------x

TRAVEL TRANSCRIPT

DEPOSITION OF MATTHEW GOODWIN
New Brunswick, New Jersey
January 17, 2006

Reported by:
MARY F. BOWMAN, RPR, CRR
JOB NO.: SE 173

GOODWIN

best answer. From time to time, Lynn, your counsel, will be entering objections to my questions and unless she instructs you not to answer, then I would ask that you try to answer the question if that's OK. Do you understand?

A. Yes.

Q. If you want me to restate a question or if you have difficulty in answering a question, I will ask you to ask me to restate it. Otherwise if you don't ask me to restate it, I will assume that you understood it. Is that fair?

A. Yes.

Q. We will be taking breaks every hour or so. If you need a break in between, let me know and we will try to accommodate you at the next convenient spot. Is that OK?

A. Yes.

Q. Is there any reason you can think of today, are there any distractions in your life or anything going on that would prevent you from giving your best testimony today, your most honest testimony today?

A. No.

Q. Can you please walk me through your

GOODWIN

education from high school, past high school.

A. I graduated from the University of Maryland with a bachelor's degree in chemical engineering. I graduated from the Temple University School of Law in 1986.

Q. Any other formal education?

A. No.

Q. And you are currently employed?

A. Yes.

Q. By whom?

A. Johnson & Johnson.

Q. Where is that?

A. In New Brunswick, New Jersey.

Q. What is your job there at Johnson & Johnson?

A. I am currently associate patent counsel, I am a patent attorney working in the law department. I have a group of patent attorneys that work for me and we support certain of the medical device companies of Johnson & Johnson.

Q. Did you have a job between law school and your job at Johnson & Johnson?

A. Yes.

Q. How many?

GOODWIN

A. I had two other positions.

Q. Can you walk me through those?

A. Yes, I worked for the Dow Chemical Company in Midland, Michigan for two and a half years. Subsequent to that, I worked for Exxon Chemical Company for about eight months before coming to Johnson & Johnson in 1989.

Q. What was your position in 1989?

A. Patent attorney.

Q. And today you are associate patent counsel?

A. Yes.

Q. Did you have any attorneys working under you in 1989?

A. No, I did not.

Q. How many do you have working under you today?

A. Four.

Q. Who is your supervisor, who is your direct boss?

A. Joseph Shirtz.

Q. How do you spell his last name?

A. S-H-I-R-T-Z.

Q. And what is his title?

GOODWIN

A. Associate patent counsel.

Q. Same title but he is your supervisor?

A. Yes.

Q. Is there a patent counsel?

A. Phil Johnson is the chief patent counsel.

Q. Did you review any materials for this deposition today?

A. Yes.

Q. And what was that?

MS. MALINOSKI: And I will instruct you not to answer based on work product. If he identifies a specific document that's OK. Otherwise, you are not entitled to that particular information.

Q. Did you review any deposition transcripts for today's deposition?

A. No.

Q. You didn't review Mr. Woodrow's deposition transcript?

A. No.

Q. You didn't review Mr. Jamialkowski's deposition transcript?

A. No.

EXHIBIT 15

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS
C.A. No. 04-12457 PBS

READ & SIGN COPY

----------x

DePUY MITEK, INC.,
a Massachusetts corporation,
Plaintiffs,
v.
ARTHREX, INC.
a Delaware Corporation,

Defendant.

----------x

DEPOSITION OF HAL BRENT WOODROW
New Brunswick, New Jersey
November 2, 2005

Reported by:
MARY F. BOWMAN, RPR, CRR
JOB NO. 97

WOODROW

A. Yes, I went to high school -- well, skip high school, start with college. Went to the University of Oklahoma in 1976, graduated with a degree in 1980 in political science, 1981 in botany, proceeded on to the University of Oklahoma Law School in 1981, graduated in 1984 with a JD.

Let's see, went to work for a law firm for a bit. Then went back to school to pick up some additional training in chemical engineering.

Q. Was that a degree, in chemical --

A. It was for a master's degree but I didn't complete the degree. I was hired by Phillips Petroleum in 1987 as a patent attorney.

Q. And you have been a patent attorney since 1987?

A. Yes.

Q. Are you registered with the patent office?

A. Yes, I am registered with the patent office. At Phillips Petroleum I worked doing biotechnology, polymers and fibers. I worked with their Phillips Fibers Division. I was with them from 1987 until 1991 when I began working with

WOODROW

Johnson & Johnson, began working for Johnson & Johnson, and I have been with Johnson & Johnson since 1991.

My first assignment at Johnson & Johnson was with McNeil Consumer which makes Tylenol and similar products and then shortly thereafter, I started working with Ethicon products or Ethicon and worked with them from 1992 until I believe it was 1999, working primarily with sutures and related inventions.

Q. Since '99, where have you been?

A. Since '99, I have been with Johnson & Johnson working in the pharmaceutical group.

Q. Is that here in New Brunswick?

A. Yes.

There is one other thing. While I was at Johnson & Johnson, you asked about educational experience. In the last couple of years, I have completed a Masters in microbiology and molecular genetics.

Q. Microbiology and molecular --

A. Genetics.

Q. Intense subject matter.

A. Yes.

WOODROW

MR. TAMBURO: I am going to ask the court reporter to mark Plaintiff's Exhibit 1 and ask you to take a look at that.

(Exhibit 1, notice of deposition marked for identification, as of this date.)

Q. Have you seen this document, Mr. Woodrow?

A. I am checking. I have seen parts of this document.

Q. Can I ask you to turn to topic 17, which is -- there is no page number, but topic 17. Do you see that?

A. Yes.

Q. Can you take a moment to review topic 17 and let me know if you are prepared to testify today on that subject matter?

A. Yes. I am prepared to testify on this subject matter.

Q. What did you do to prepare to testify on that subject?

A. I reviewed a document and discussed --

MS. MALINOSKI: I will caution you to the extent that you would reveal any privileged communications, not to reveal the

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substance of any privileged communication.

A. Let me rephrase the question -- rephrase the answer. I have reviewed a document and knowledge related to Ethicon's licenses related to sutures.

Q. Maybe I misunderstood. You reviewed a document and knowledge related to -- I thought that's what you said?

A. Yes.

Q. Did you speak with anybody at Ethicon to prepare for this topic?

A. I spoke with one of the attorneys at Ethicon.

Q. Who was that?

A. Matt Goodwin.

Q. Matt Goodwin?

A. Um-hm.

Q. Who was he?

A. He is one of the patent attorneys that works at Ethicon.

Q. Is he your supervisor?

A. No.

Q. How many patent attorneys are at Ethicon today?

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statements made regarding what Kaplan does not teach?

A. Yes.

Q. Did Ethicon still believe that Kaplan did not teach or suggest how its sheath yarn component is to be fabricated from the dissimilar individual filaments and that Kaplan didn't provide any guidance as to how the dissimilar individual filaments are to be braided?

MS. MALINOSKI: I think that's asked and answered.

Q. Let me restate that. At the time the amendment was made, August 3, 1993, did Ethicon still believe that Kaplan was a deficient reference and decided to amend anyway?

MS. MALINOSKI: Objection. And again, same objection based on privileged and work product.

Again, if you don't think you could answer that based on privilege or work product, then I will instruct you not to answer.

A. I believe you are asking for a statement of mental state at the time I signed the amendment which I believe would be privileged work

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product.

Q. OK. So you are not going to answer on those grounds?

A. Yes.

Q. Do you know why Ethicon put you in charge of this case and removed Mr. Goodwin?

A. Mr. Goodwin took another assignment in Cincinnati.

Q. Mr. Goodwin is no longer with Ethicon?

A. Mr. Goodwin went to Cincinnati to work with Ethicon Endo and then returned later to work again with Ethicon.

Q. So he moved, changed jobs basically, that's why he was removed from the application, from prosecuting the application?

A. That's why he ceased prosecuting. I don't know whether removed -- he went on to another job.

Q. Was this claim 21 amended to overcome the rejection based on Kaplan?

MS. MALINOSKI: To the extent that calls for privileged or work product information, I instruct you not to answer. But otherwise, you can.

WOODROW

A. The amendment states the claims have been amended -- the amendment claims claim 21 has been replaced to has been re-- the amendment states that claim 21 has been amended to place this claim in proper form for allowance further. In discussing Kaplan, it says --

Q. Where are you reading from, sir?

A. DMI 259.

Q. Where?

A. About third paragraph, "Further it states applicant submits that claim 21 has been and is not anticipated by Kaplan and amended."

Q. So the intent to was to amend to overcome the rejection based on Kaplan?

MS. MALINOSKI: Objection, mischaracterizes his testimony.

A. There are two rejections in front of -- that this amendment deals with and the first one talks, the first paragraph I read talks about Kaplan. And the second reference, the second argument I think says -- it says, "However applicants submit that claims 21 through 4 are patentable over these documents" -- right, those would be the amended claims.

WOODROW

Q. Was Ethicon's understanding at the time it drafted this response, this amendment, that Kaplan did not disclose a sheath yarn that contained only nonbioabsorbable material?

MS. MALINOSKI: Objection, vague.

Q. Let me ask a better question.

What was Ethicon's belief as to what Kaplan taught regarding the materials on the sheath of Kaplan?

A. That the sheath yarn is a biocompatible -- the sheath yarn is biocompatible and it is bioabsorbable or semibioabsorbable.

Q. Where are you reading from?

A. See below, DMI 259, paragraph -- third paragraph.

Q. The next sentence says, "Claim 21 as amended does not claim a sheath yarn composed of a bioabsorbable yarn." Do you see that?

A. Yes.

Q. Does that imply that Kaplan does have a bioabsorbable yarn in its sheath?

A. Yes. It is -- what is said above. The sheath yarn being biocompatible -- biocompatible yarn that is bioabsorbable or